APPENDIX B – Engineering Specifications

Procedure	Revision	Issue Date	Originator : Engineering
S-001	00	7/11/96	Michael J. Pappas

ENDOTEC, INC.

20 Valley Street, South Orange , New Jersey 07079

SPECIFICATION # S-001

Specification Title: **Solution Treatment And Aging Of Titanium Implants.**

1. SCOPE

1.1 This specification applies to the general process and quality assurance requirements for the heat treatment of ASTM F67, ASTM F1108 ,and ASTM F136 Surgical Implants. This shall apply where it is specified on engineering drawings, process routers or purchase orders.

2. [illegible] SCOPE

2.1 This specification specifies the general process and documentation requirements for Solution Treat and

3. APPLICABLE DOCUMENTS

3.1 [illegible] cification of general requirements for a quality control system.

3.2 [illegible] Heat treatment of titanium and titanium alloys.

3.3 [illegible] pecification for Ti-6Al-4V ELI alloy for surgical implant applications.

3.4 [illegible] pecification for unalloyed titanium for surgical implant.

3.5 [illegible] pecification for Ti-6Al-4V alloy castings for surgical implants.

3.6 [illegible] thods of tension testing of metallic materials.

3.7 [illegible] Test method for tension testing of porous metal alloys.

4. [illegible] PROCEDURE DEFINITION

4.1 [illegible] shall be fixtured and properly identified in a vacuum chamber per vendor customary

4.2 [illegible] shall be solution treated at a process temperature of 1880F [illegible] minimum maintained for 1 hour while at process temperature. The process parameters shall be maintained for a [illegible] 60 minutes soak time.

4.3 [illegible] shall be argon quenched from process temperature to below 1100F at a minimum cooling rate.

	Procedure	Revision	Issue Date	Originator : Engineering
	-001	00	7/11/96	Michael J. Pappas

4.4. The implants are to be aged at a process temperature of 1150F and a minimum maintained vacuum of 10 - [illegible] process temperature. The process parameters shall be maintained for a period of two (2) [illegible]

4.5. The components are to be argon cooled from process temperature to below 600F and air cooled thereafter.

5. QUALITY ASSURANCE PROVISIONS

5.1. The vendor is to comply with all quality assurance provisions for equipment and materials.

5.2. The vendor shall supply all necessary samples required to perform post heat treatment mechanical and [illegible] examination.

5.3. The post heat treated micro structure shall consist of a fine Widmanstatten morphology . The structure [illegible] free of alpha case and with no continuous alpha phase along grain boundaries. At the discretion [illegible] vendor shall perform and submit metallogaphic evidence and test results of the post head [illegible] structure.

5.4. [illegible] testing shall be performed as per ASTM-F 1147 for porous coated and ASTM-E 8 for non [illegible] implants.

[illegible] DOCUMENTATION

[illegible] provide certification that shall include but not be limited to the following:
- [illegible] this specification and statement of compliance.
- [illegible] Heat treatment Lot Number.
- [illegible] Order number.
- [illegible] Processed by Lot number.
- [illegible] Document tension test results.

[illegible] 2) test specimens shall be returned with the processed [illegible]

[illegible] in the process and test records in perpetuity. Where the vendor is unable to [illegible] document requirement, such records shall be transferred to [illegible] for retention.

The vendor shall provide evidence of a quality program as defined in ANSI/ASQC-C1-1985, or [illegible] Evidence may include, but not limited to, certification of [illegible] and NIST [illegible] all controlling and monitoring equipment used in this process.

REJECTION / REWORK

[illegible] compliance to this specification shall be rejected.

[illegible] shall be subject to engineering review to determine whether rework shall be authorized. [illegible] work is allowed, all applicable test and documentation shall be repeated for the [illegible]

Procedure	Revision	Issue Date	Originator : Engineering
S-002	00	10/3/95	Michael J. Pappas

ENDOTEC, INC.

20 Valley Street, South Orange , New Jersey 07079

SPECIFICATION # S - 002

Specification Title: **Blue And Clear Anodized Aluminum Instrumentation.**

1. SCOPE

1.1 This specification applies to the general practice and process for the surface finish by anodizing of instrumentation parts to be used as instrumentation.

2. PURPOSE

2.1 This specification specifies general practice requirements for surface preparation, method of surface finishing of instrumentation. This shall apply when referenced on engineering drawings, part and or purchase orders.

3. APPLICABLE DOCUMENTS

Specification of General Requirements for a Quality

Practice for the Care and Handling of Orthopedic Implants and Instruments.

Type II Sulfuric Acid Anodizing

tion for Good Manufacturing Practices.

ification

4. DEFINITIONS

ument is defined by F565 as a device used during a surgical procedure.

5. PREPARATION AND INSPECTIONS

5.1 Preparation:

surface to be anodized shall have a uniform finish. Uniformity is referred to here as the only one type tool or finishing process. For example a part shall not have part of the machined and part sanded. It is thus recommended that a burnished or sandpaper rubbed shall be used on all aluminum parts. Where part geometry permits the riginal machined may be maintained if such surface has a finish of sixteen micro inches or better.

5.2 Anodizing:

5.2.1 Anodizing may be performed by sulfuric acid anodizing per MIL-A-8625 Type II. Unless specified by engineering or purchase order documentation no clear anodizing shall be less than 0.0007"

5.2.2 Color shall be Medium Cool Gray 1 to 4 as defined by PMS.

5.3

TEG	Procedure	Revision	Issue Date	Originator : Engineering
	S-002	00	10/3/95	Michael J. Pappas

5.2.1. Blue anodizing may be performed by sulfuric acid anodizing per MIL-A-8625 Type II. Unless otherwise specified by engineering or purchase order documentation no blue anodizing shall be thinner than 0.0007".

5.3.2. The final color shall be controlled to Panatone Process Blue as defined by PMS.

5.4. All parts shall be inspected by the anodizing facility for any visible surface defects or poor surface condition. Such inspection is to identify an transportation damage to the parts.

5.5. All parts shall be inspected by the anodizing facility for poor anodized surface condition such as discoloration or non anodized areas.

REPORTING AND DOCUMENTATION

6.1. All parts shall be processed according to S-016.

REJECTION & REWORK

7.1. Parts not meeting this specification may be stripped and reanodized unless otherwise specified by the purchasing documentation or engineering specification.

Specification	Revision	Issue Date	Originator: Engineering
S-003	A	3/12/99	Michael J. Pappas

ENDOTEC, INC.

20 Valley Street, South Orange , New Jersey 07079

SPECIFICATION # S-003

Specification Title: **Blue Anodizing Process of Ti-6Al-4V Orthopedic Instruments.**

1. SCOPE

1.1 This specification applies to the general practice and process for the blue coloring of Ti-6Al-4V orthopedic instrumentation.

2. PURPOSE

2.1 This specification specifies general practice requirements for surface characteristics, method of surface preparation and finishing of Ti-6Al-4V instrumentation specified with a blue surface color. This shall apply when referenced on engineering drawings, process routers and or purchase orders.

3. APPLICABLE DOCUMENTS

3.1 ISO 9001 Specification of general requirements for a quality control program.

3.2 AMS-2488 Anodic Treatment, Titanium and Titanium Alloys.

3.3 ASTM-F565 Practice for the care and handling of orthopedic implants and instruments.

3.4 FDA specification for Good Manufacturing Practices.

3.5 PMS color definition

4. DEFINITIONS

4.1 Orthopedic surgical instrument is defined by F565 as a device used during a surgical procedure involving the implantation of orthopedic implants.

5. PROCESS AND INSPECTIONS

5.1 Surface requirements

5.1.1 The RMS of the surface to be blued shall conform to the engineering drawing requirements. It is recommended that where part geometry permits the original machined surface may be maintained if such surface finish is 16 RMS or better. Highly polished surfaces are not recommended as surface etching during the process may degrade it.

5.1.2 An anodic treatment process shall be employed to coat deposit a single layer of titanium oxide on the entire surface of the part. Unless otherwise specified by engineering or purchase order instrumentation the coating shall meet AMS-2488.

5.1.3 The final color shall controlled to Panatone Blue 293 or 300 as defined by PMS.

5.2 Parts shall be inspected by the processing facility for any visible surface defects or poor surface finish. Such inspection is to identify any transportation damage to the parts.

Specification S-063	Revision A	Issue Date 3/12/99	Originator: Engineering

5.3. All parts shall be inspected by the processing facility for poorly plated surface condition such as discoloration.

5.4. Final color being a function of coating thickness and surface texture, all parts shall be processed based on prior sample approval.

6. REPORTING AND DOCUMENTATION

6.1. All parts shall be processed according to S-016.

7. REJECTION & REWORK

7.1. Parts may be striped and recoated unless otherwise specified by the purchasing documentation or engineering specification.

Procedure	Revision	Issue Date	Originator : Engineering
S-005	00	10/3/95	Michael J. Pappas

ENDOTEC, INC.

20 Valley Street. South Orange . New Jersey 07079

SPECIFICATION # S-005

Specification Title: **Permanent Marking of Finished Orthopedic Implants and Instrumentation.**

1. SCOPE

1.1. This specification applies to the general practice and process for marking Implants and Instrumentation. This specification shall apply when referenced on engineering drawings, process routers and or purchase orders.

2. PURPOSE

2.1. This specification specifies general practice requirements for surface characteristics, method of surface preparation and marking of Implants and Instrumentation.

3. APPLICABLE DOCUMENTS

Specification of General Requirements for a Quality Control System.

Practice for the Care and Handling of Orthopaedic Implants and Instruments.

Specification for Ti-6Al-4V ELI alloy for Surgical Implant Applications.

Standard Guide for the Permanent Marking of Orthopaedic Implant Components

Specification for Ti-6Al-4V alloy Castings for Surgical Implants

Practice for Surface Preparation and Marking of Metallic Surgical Implants

Regulation for Good Manufacturing Practices.

4. DEFINITIONS

4.1. Surgical implant is defined by F565 as a device introduced by surgically penetrating the skin or body with the intention that it remain within the body following surgery.

4.2. Instrument is defined by F565 as a device used during a surgical procedure.

5. PROCEDURE / PROCEDURE DEFINITION

5.1. Laser Marking

5.1.1. Marking shall be performed by the use of a high energy focused laser beam. The beam diameter shall be .003" at a perpendicular plane. Where marking lines wider than .003" are required, the marking must be use a wobble format to achieve the required area coverage required.

5.1.2. The laser beam method is a non-contact line of sight marking method, marking surface irregularities and compensation are not necessary. All characters and symbols shall be applied to surfaces in their normal plane view or as prescribed by the engineering drawing plane views.

5.1.3. Variations resulting from local part surface geometry are allowed to the extent that the resulting marking meets the legibility requirements of this specification.

Procedure	Revision	Issue Date	Originator : Engineering
S-005	00	10/3/95	Michael J. Pappas

5.2. Tool engraving

5.2.1. Marking may be performed by the use of a round rotating Burr , or radiused Half spade Engraving tool. The tool tip radius shall not be less than 0.008". Marking line width shall be defined by the letter type and size specification. Marking line width to depth ratio shall always be greater than one. Unless otherwise specified by engineering or purchase order documentation no marking shall be made deeper than 0.015" . Specified line widths shall be achieved by multiple passes at the appropriate offsets for wide formats. or reduction of tool depth in narrow line formats. This marking method may generate burrs that are to be removed in a manner that would not deface the marking.

5.3. **Mechanical Imprinting.**

5.3.1. Mechanical imprinting is performed though pressure deformation of the surface. All marking shall result in round-edged and bottom markings and lettering. The average depth of such markings shall not exceed 0.005".

6. GENERAL GUIDELINES

6.1. Marking Location

6.1.1. Marking Location on implants and instruments shall be specified as per standard practice F86 at locations that do not compromise the part integrity and provide visibility. Such locations shall be specified on the engineering drawings.

6.2. Marking Format

6.2.1. Manufacturer's Logo: This information shall be marked on all parts using the format indicated in Appendix A1. The location and height of the logo shall be specified on the engineering drawing.

6.2.2. Part **Information.**

6.2.2.1. All other information to be included in the permanent marking of parts shall be Part specific information. All character fonts used shall be Helvetica Proportional. The actual size shall be defined by the font size, and indicated on the engineering drawing. The location of such information shall be specified by the engineering drawing of the part. The information referred to in this section shall be:

Component Lot Number. The lot number is an assigned number for tracking material traceability and implant specific information. This number is unique to a specific lot of parts and is required on all purchasing and shipping documentation. The lot numbers are generated and maintained as per S-016. The number format is depicted in appendix A2

Size. The size of the Component as indicated by the purchase order documentation and required in both part number and lot number is to be in the millimeter format as depicted in appendix A3.

6.3. Marking Type Selection:

6.3.1. Ti-6Al-4V Implants: Ti-6Al-4V implants shall be marked using the laser etching method. The resulting mark shall be dark blue to bark brown color.

6.3.2. CoCr Implants: CoCr implants shall be marked using the laser etching method. The resulting mark shall be dark blue to dark brown color.

6.3.3. UHMWPe Implants : UHMWPe Implants shall be marked by engraving or mechanical imprinting.

6.3.4. Stainless Steel: Stainless steel shall be marked using the laser etching method. The resulting mark shall be dark brown color. Where the size of the part is to be marked and such marking is to be in vicinity of articulation surfaces that are to be in contact with other instruments then it is recommended that engraving at the maximum permitted depth is used.

ENDOTEC	Procedure	Revision	Issue Date	Originator : Engineering
	S-005	00	10/3/95	Michael J. Pappas

6.3.5. TiN coated surfaces: All TiN coated surfaces shall be laser etched. The resulting mark shall be dark blue to dark brown in color.

6.3.6. Blue Anodized Aluminum: All blue anodized surfaces shall be laser etched resulting in a silver metallic marking.

6.3.7. Blue Ti-6Al-4V: All blue Ti-6Al-4V parts shall be marked by engraving. The resulting mark shall be silver to metallic gray in color.

7. INSPECTION:

7.1. Receiving

7.1.1. All parts shall be inspected by the marking vendor for any visible surface defects or poor surface condition. Such inspection is to identify an transportation damage to the parts.

7.1.2. All Lot numbers are to be verified and cross referenced between the individual parts and the supporting part number documentation.

8. REPORTING AND DOCUMENTATION

8.1. All parts shall be processed according to S-016.

9. REJECTION & REWORK

9.1. [illegible] be reworked unless otherwise specified by the purchasing documentation or engineering [illegible]

9.2. [illegible] reworked in such a manner as to result in mislabeling.

	Procedure	Revision	Issue Date	Originator : Engineering
BIOTEC	S-005	00	10/3/95	Michael J. Pappas

APPENDIX A1 Manufacturer Logo

APPENDIX A2 Lot Number

APPENDIX A3 Size

Specification	Revision	Issue Date	Originator: Engineering
S-006	A	7/7/97	*Michael J. Pappas*

ENDOTEC, INC.

20 Valley Street, South Orange , New Jersey 07079

SPECIFICATION # S-006

Specification title: Specification for Ti6Al4V Alloy Castings for Surgical Implants.

1. SCOPE

1.1 This specification provides material and processing requirements for Ti6Al4V alloy castings to be used in the manufacture of surgical implants.

2. APPLICABLE DOCUMENTS

2.1 ASTM Standards:

B367 Standard Specification for Titanium and Titanium Alloy Castings
B600 Standard Guide for Descaling and Cleaning Titanium and Titanium Alloy Surfaces
E8 Standard Test Methods for Tension Testing of Metallic Materials
E120 Standard Test Methods for Chemical Analysis of Titanium and Titanium Alloys
E1409 Standard Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique
E1447 Standard Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method
F136 Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications
F1108 Standard Specification for Ti6Al4V Castings for Surgical Implants

2.2 Ref Standards:

AMS 4991 A Titanium Alloy Castings, Investment: 6Al-4V: Annealed
ANSI/ASQC Q9001-1985 Specification of General Requirements for a Quality Control Program
S-007 Endotec Visual and Fluorescent Penetrant Inspection for Ti6Al4V Alloy Castings for Surgical Implants
S-008 Endotec Radiographic Inspection for Ti6Al4V Alloy Castings for Surgical Implants
S-016 Endotec General Guidelines in Good Manufacturing Practices
Endotec Inspection Procedures

3. PROCEDURE

3.1 All cast parts shall be manufactured using the Good Manufacturing Practices Guidelines established in Endotec Specification S-016. Specification S-016 shall be used as an operating guideline for all personnel and organizations that come into contact with Endotec cast parts including all subcontractors and their personnel. All subcontractors utilized by the primary manufacturer must be disclosed to Endotec prior to any contracted processing on Endotec parts. All subcontractors must be approved by Endotec in written form and the subcontractors and their quality system must be made available to an audit performed by Endotec.

3.2 All cast parts shall be documented and controlled through lot numbering. Lot numbers shall be assigned as the initial step to all processing. Distinct lot #'s shall be assigned to each individual metal pour. All certification shall be referenced to each discrete lot number. All cast parts from each lot shall be accounted for at the completion of processing. Disclosure of accounting of all parts shall be available to Endotec when requested in written form.

3.3 Each lot shall be cast with tension test specimens (Figure 1) and chemical analysis specimens (Figure 2). The test specimens will be documented and shipped with the final cast parts. One tension test specimen and one chemical analysis specimen will constitute one set of test specimens. The tension test specimens will be processed through all thermal cycles that the cast parts are processed through. The use of chemical milling on tension test specimens will be determined by dimensional conformance to Figure 1. Excess material shall be removed in the region described by dimension 'D.' The minimum required amount of excess material shall

ENDOTEC	Specification	Revision	Issue Date	Originator: Engineering
	S-006	A	7/7/97	*Michael J. Pappas*

be 0.030" across the diameter. Conformance to other Figure 1 dimensions shall be determined by the ability to finish the as-cast specimen to the finished dimensions. The use of chemical milling on tension test specimens is not required. Chemical analysis coupons will be processed through all thermal cycles and chemical milling cycles that the cast parts are processed through. It is assumed that chemical composition and mechanical properties exhibited by the specimens will be the same as the properties and composition of the cast parts. On lots of less than 50 pieces the casting manufacturer will provide two sets of test specimens; on lots of 50 or greater pieces the casting manufacturer will provide three sets of test specimens.

3.4 All cast parts shall be manufactured to an investment cast form under vacuum. Vacuum levels shall be maintained at a minimum vacuum level of 250 µm of Mercury during the stage of the casting cycle that is characterized by the melting of the raw material ingot and the physical pouring of the mold. After completion of the physical pour, the vacuum level shall be maintained at a minimum vacuum level of 250 µm of Mercury for a period of time deemed necessary to prevent excessive contamination of the cast parts.

3.5 All cast parts shall be provided with gating removed. Gating includes all attachments that do not conform to the Endotec Drawing Specification. Removal of gating should be done in such a way that ensures the cast part profile is not violated. Refer to the Endotec Inspection Procedures for cast part specifications on permissible height of gate stub for shipment.

3.6 All thermal processing done on the cast parts shall be performed either under vacuum or under an inert gas atmosphere consisting of Argon. Thermal processing shall be defined as any processing in which temperature of the cast part exceeds 1000 °F. Known thermal processing includes but is not limited to welding processing, HIP processing, and any heat treatment cycle. Vacuum levels shall be maintained at a minimum of vacuum level of 0.5 µm of Mercury through any thermal cycles. Argon gas used as an inert atmosphere shall be defined as a minimum of 99.98% pure. Maximum acceptable impurity levels of Argon gas shall be available to Endotec when requested in written form..

3.7 Only virgin material shall be used in the direct manufacture of any Endotec cast parts. Virgin material is defined as material that has not been subject to temperatures in excess of 1000 °F and has not been subject to a complete chemical analysis. In the presence of complete chemical analysis and mechanical properties certification, material shall be assumed to be a certified master heat.

3.8 Chemical composition of all cast parts shall conform to the most current, commercially available version of ASTM F1108. Conformance to ASTM F1108 shall be determined by a standard testing method as described in ASTM F1108. Conformance to ASTM F1108 for the acceptable amounts of Oxygen shall be determined by a standard testing method as described in ASTM E1409. Conformance to ASTM F1108 for the acceptable amounts of Nitrogen shall be determined by a standard testing method as described in ASTM E1447. The chemical composition of the material shall be certified by both the ingot manufacturer and the casting manufacturer. The casting manufacturer may submit a chemical analysis of each lot that consists of only the gaseous elements Hydrogen, Nitrogen, and Oxygen. The casting manufacturer's chemical analysis that is to be submitted to Endotec shall be done after all thermal processing and after any other manufacturing processes, including but not limited to chemical milling, that may alter the chemical composition of the cast part.

3.9 Mechanical properties of all cast parts shall conform to the most current, commercially available version of ASTM F1108. Conformance to ASTM F1108 shall be determined by a standard method as prescribed in ASTM F1108. The casting manufacturer may submit mechanical certification from the master heat except in the presence of unacceptable changes of chemical analysis between master heat and casting lot. Any mechanical certification shall be done after all thermal processing is completed.

3.10 Microstructure of cast parts shall be subject to a metalographic analysis after all thermal processing has been completed. The metalographic analysis shall be performed on a representative sample under 100X magnification to determine the depth or extent of the oxygen enriched, α-phase stabilized layer or surface that is commonly referred to as α-case. Preparation of the metalographic sample must be done in a manner which retains the original microstructure of the sample. All cast parts shall be provided to Endotec in a condition that is free of α-case. The definition of α-case free includes the removal of all spikes that are known to occur.

3.11 All cast parts shall be processed through a hot, isostatic, thermal cycle that is commonly referred to as HIPping. HIP processing shall be defined as thermal processing at temperature of 1650 °F +/- 25 °F for a minimum of 2 hours to 4 hours at a maintained argon pressure of 15KSI +/- 0.5KSI. HIP processing shall result

ENDOTEC	Specification	Revision	Issue Date	Originator: Engineering
	S-006	A	7/7/97	*Michael J. Pappas*

in the dissolving of any microconstituents deposited on any internal pore surfaces. All cast parts shall be furnace cooled in an argon atmosphere from the process temperature of 1650°F +/- 25°F down to a process temperature of at least 1000°F after which the cast parts may be air cooled to room temperature

3.12 All cast parts shall be subject to visual and liquid penetrant examination in accordance with Endotec Process Specification S-007. Items rejected under the requirements of S-007 shall be handled as described in Section 7.0 Rejection and Rework. All cast parts must be accepted under the requirements of S-007 prior to shipment as accepted parts.

3.13 All cast parts shall be subject to radiographic examination in accordance with Endotec Process Specification S-008. Items rejected under the requirements of S-008 are not subject to rework without express written consent from the Endotec Quality Department. All cast parts must be accepted under the requirements of S-008 prior to shipment as accepted parts.

3.14 All cast parts shall be provided in the cleaned and descaled state as described in ASTM B600.

3.15 All cast parts shall be shipped to Endotec in a manner that prevents physical damage to the individual parts. Packaging shall consist of a cardboard box that is suitable for land based shipping, an internal lining if necessary to ensure cast parts are not lost in the case of box damage, and internal padding to divide or separate individual cast parts. All packaging should be designed to minimize the risk of physical damage to cast parts from each other and also from sources outside the packaging. All packaging materials shall be submitted to the Endotec Quality Department for a written acceptance.

3.16 All cast parts shall be processed to meet Endotec Engineering Drawing specifications.

3.17 All cast parts shall conform Endotec Process Specifications S-006, S-007, S-008, and S-009. Any deviations from conformance to these specification shall be brought to the attention of the Endotec Quality Control Department in written form. Cast parts that do not meet any aspect of these specifications will not be shipped without written consent by the Endotec Quality Department.

4.0 QUALITY ASSURANCE PROVISIONS

4.1 The casting manufacturer shall maintain a quality program such as defined in ASQC Q-90 or equivalent.

5.0 INSPECTION REQUIREMENTS

5.1 Dimensional Inspection

5.1.1 The casting manufacturer will be provided with the Endotec Inspection Procedures. The procedures will give detailed instructions on inspection techniques and equipment and shall pertain to multiple sizes of cast parts that are described by the same Endotec Engineering Drawing. The Endotec Inspection Procedures shall be used as the guidelines for the casting manufacturers to perform in-process and final dimensional inspection. The Endotec will provide the casting manufacturer with the Endotec Inspection Report to be utilized for the final dimensional inspection. Specifications on the Endotec Inspection Report may deviate from the Endotec Engineering Drawing specifications. The Endotec Inspection Report specifications shall be used in cast part dimensional inspections.

5.1.2 The casting manufacturer will use an acceptable sampling plan to generate dimensional data for each lot in the as-cast and in the as-cast condition prior to chemical milling or any thermal processing. The Endotec Inspection Report will be utilized to generate the final dimensional inspection in the finished condition after chemical milling. All dimensional data will be available to the Endotec Quality Control Department upon written request.

5.1.3 In the situation where the presence of weld repairs hinders the Endotec Inspection Procedure, the presence of the weld repair shall be noted in the cast part dimensional inspection. Refer to Table 2 in S-007 for allowable configurations of weld repairs.

5.2 Surface Inspection

5.2.1 All cast parts shall be inspected for surface defects in accordance with S-007.

5.3 Radiographic Inspection

5.3.1 All cast parts shall be inspected for sub-surface defects in accordance with S-008.

6.0 REPORTING AND DOCUMENTATION

6.1 The casting manufacturer shall identify each lot with the manufacturer's name, manufacturer's work order

ENDOTEC	Specification	Revision	Issue Date	Originator: Engineering
	S-006	A	7/7/97	*Michael J. Pappas*

number, serial numbers corresponding to the radiographic examination, and the master heat lot number in accordance with ASTM B367.

6.2 The cast parts shall be lot controlled through all processing. Lot number shall be referred to on all certificates of conformance and clearly marked on each cast part prior to shipping. Marking the cast parts with radiographic inspection serial numbers may be substituted for individually marking each cast part with lot numbers. Any marking must be clearly displayed and easily traceable to original lot numbers.

6.3 The casting manufacturer shall perform and certify all tests and processes required by ASTM B367, ASTM F1108 and this specification. Certificates of conformance to the above shall contain, but not be limited to:

a) Chemical analysis of master heat in accordance with ASTM F1108
b) Gaseous Chemical analysis of cast parts in accordance with ASTM F1108
c) Mechanical properties of master heat in accordance with ASTM F1108
d) Final dimensional analysis in the form of the Endotec Inspection Report
e) Surface condition test reports of cast parts in accordance with S-007
f) Radiographic test reports of cast parts in accordance with S-008

7.0 REJECTION AND REWORK

7.1 All cast parts rejected for surface discontinuities either in visual inspection or fluorescent penetrant inspection may be repaired by welding. All welding processing will be of the inert-gas-tungsten-arc method commonly referred to as GTAW. GTAW welding is defined as a thermal process and therefore is governed by the conditions as described in section 3.6.

7.2 Casting manufacturer shall submit a procedure to Endotec for written approval all GTAW rework processing. Procedure shall include but not be limited to personnel qualifications, material usage and control (i.e. shielding gas, electrode, filler material, cleaning agents, etc.), equipment usage and control including any cast part fixturing, actual welding procedure, and quality assurance system.

7.3 [illegible] done with the following restrictions on the surfaces as defined in paragraph A of S-007.
[illegible] - Wrought material conforming to ASTM F136 shall be used with no exceptions.

7.4 [illegible] rejected in dimensional inspection for straightness or rejected in dimensional inspection for [illegible] may be subject to rework. Mechanical straightening or any type of coining operation must be approved in written form by Endotec on an individual lot basis. If it is determined that the rework operation [illegible] operation on other lots, the rework operation may be approved in the written form for an [illegible] time.

7.5 [illegible] requiring weld repair or mechanical straightening shall be subject to a stress relief, annealing [illegible] for rework. Casting manufacturers must meet the requirements of AMS 2801 A, Section 3.5 on [illegible]. Process parameters for the stress relief cycle shall be defined as heating the cast parts in an [illegible] furnace or maintained vacuum of 0.5 µm of Mercury to a temperature in the range of 1300°F - 1550°F, soaking at the selected temperature within ±25°F for 2 to 4 hours, furnace cooling to at least a temperature of 1000°F and air or equivalent to air cooling to room temperature. Furnace cooling from the selected soak temperature of 1300°F - 1550°F +/- 25°F should be a uniform cooling that is done in a manner that does not impart any thermal related, residual stresses. A HIP cycle as defined by section 3.11 may be used in place of the stress relief, annealing thermal cycle.

7.6 All rework cycles shall be performed on the cast parts prior to final visual inspection, final penetrant inspection, final radiographic inspection, and final dimensional inspection.

Specification	Revision	Issue Date	Originator: Engineering
S-007	C	8/16/99	*Michael J. Pappas*

ENDOTEC, INC.

20 Valley Street, South Orange , New Jersey 07079

SPECIFICATION # S-007

Specification title: Visual and Fluorescent Penetrant Inspection for Ti6Al4V Alloy Castings for Surgical Implants.

1.0 SCOPE

1.1 This specification defines the visual acceptance criteria and the fluorescent penetrant inspection criteria for Ti6Al4V alloy castings to be used in the manufacture of surgical implants.

2.0 APPLICABLE DOCUMENTS

2.1 ASTM Standards:

B600 Standard Guide for Descaling and Cleaning Titanium and Titanium Alloy Surfaces

E165 Standard Practice for Liquid Penetrant Examination.

F601 Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

2.2 Other Standards:

ASNT TC-1A Supplement D Recommended Practice, Personnel Certification and Certification in Non-Destructive Testing

ANSI/ASQC Z1.15-1968 Specification of General Requirements for a Quality Control Program

NAS 410 (NAS) Certification & Qualification of Nondestructive Test Personnel

[illegible] Endotec specification for Ti6Al4V Alloy Castings for Surgical Implants

21 CFR Endotec general guidelines in Good Manufacturing Practices

3.0 QUALIFICATION OF INSPECTION PERSONNEL

3.1 All inspection personnel who may be responsible for any cast part inspection shall have a minimum vision rating as follows:

a. Near vision: Titmus Vision Tester 20/25 or better

b. Near vision acuity: Jaeger Type 2 at 14 inches or better

c. Color vision: Average(4 of 6 responses on Titmus test)

3.2 Inspection personnel performing fluorescent penetrant inspection shall be qualified in accordance with MIL STD 410 and or ASNT TC-1A Supplement D.

4.0 PENETRANT MATERIAL AND METHODS

4.1 All cast parts shall be processed in accordance with ASTM F601.

4.2 All fluorescent penetrant materials shall conform to the latest version of MIL STD 6866 Type 1 and be of sensitivity Level 2 or greater. All fluorescent penetrant materials used on the cast parts shall be of the water washable type unless express written permission is granted for use of other materials.

4.3 Final fluorescent penetrant inspection shall be performed after all thermal processing, chemical milling, or surface conditioning processes are completed.

4.4 Fluorescent penetrant inspection shall be performed under black light with a minimum intensity of 1600μW/cm^2 at a distance of 2 inches.

4.5 Cast parts shall have surface definitions as found in Appendix A. Surface definitions shall be used in determining visual and fluorescent penetrant inspection acceptance criteria and rework instructions.

5.0 GENERAL [illegible] INSPECTION

Specification	Revision	Issue Date	Originator: Engineering
S-007	C	8/16/99	*Michael J. Pappas*

5.1 All cast parts shall be inspected under white light at 1X magnification.

5.2 Final visual inspection shall be performed after cast parts are cleaned and desiccated in accordance with ASTM B600.

5.3 Visual cast part acceptance shall be in accordance with S-007, Table 1. The surface definitions referred to in Table 1 are found in Appendix A.

5.4 Acceptable configurations of weld repairs shall be found in S-007, Table 2. The surface definitions referred to in Table 2 are found in Appendix A.

5.5 Surface roughness for all cast parts shall be characterized as a maximum surface finish of 125 RMS in the cleaned and descaled condition.

6.0 QUALITY ASSURANCE PROVISIONS

6.1 The casting manufacturer shall maintain a quality program such as defined in ASQC C1-1985 or equivalent.

7.0 REPORTING AND DOCUMENTATION

7.1 The casting manufacturer shall perform and certify all tests and processes required by this ASTM F601 and this specification. Certificates of conformance to the above shall contain, but not be limited to:

a) Fluorescent penetrant testing of cast parts in accordance with ASTM F601
b) Fluorescent penetrant materials in accordance with MIL STD 6866
c) Fluorescent penetrant Inspection acceptance of cast parts in accordance with Table 1
d) Surface finish testing of cast parts in accordance with S-007
e) Visual Inspection acceptance of cast parts in accordance with Table 1
f) Weld repair configuration acceptance of cast parts in accordance with Table 2

8.0 REJECTION AND REWORK

8.1 Rework on cast parts in the form of weld repairs shall be processed in accordance with S-006. Surface definitions for weld mapping shall be found in Appendix A. Acceptable configurations of weld repairs shall be found in Table 2.

Specification	Revision	Issue Date	Originator: Engineering
S-007	C	8/16/99	*Michael J. Pappas*

Table 1
Surface Discontinuity Acceptance Criteria

Positive Discontinuities

	Surface 1	Surface 2	Surface 3
Surface Name	Articulating/Polished Surface	Porous Coated Surface	Edges/Polished Surface
Maximum Height	0.010	0.010	0.010
Maximum Qty/Area	3/in^2	3/in^2	3/in^2

Negative Discontinuities

	Surface 1	Surface 2	Surface 3
Surface Name	Articulating/Polished Surface	Porous Coated Surface	Edges/Polished Surface
Maximum Diameter	0.010	0.020	0.010
Maximum Depth	0.005	0.010	0.005
Maximum Length	0.010	0.020	0.020
Maximum Qty/Area	2/in^2	3/in^2	3/in^2
Minimum Spacing	3X	3X	3X

Notes:

1. No cold shuts, cold shots, aligned oxide inclusions, cracks, or other linear inclusions shall be allowed. A linear inclusion is defined as an inclusion where the length divided by the average width is greater than 3.
2. No discontinuities with sharp cornered features are permitted. Sharp corners are defined as corners with less than a 0.005" radius.
3. Depth of a discontinuity may be assumed to be 1/2 of the discontinuity diameter.
4. Lengths may be assumed to be the diameter of the circle that encompasses the discontinuity.
5. Depth and height of a discontinuity should be measured or referenced from the defined profile of the cast part.
6. Non-interpretable discontinuities defined to be less than 0.010 diameter.
7. Combinations of discontinuities are permissible in the same area provided the total number and spacing of discontinuities does not exceed what is permitted for any one type of discontinuity.
8. All dimensions are in inches.

Specification	Revision	Issue Date	Originator: Engineering
S-007	C	8/16/99	Michael J. Pappas

Table 2
Weld Repair Acceptance Criteria

Positive or Filler Rod Weld Repairs

	Surface 1	Surface 2	Surface 3
Surface Name	Articulating/Polished Surface	Porous Coated Surface	Edges/Polished Surface
Maximum Height	0.015	0.010	0.010
Maximum Length	0.250	0.500	0.375
Maximum Qty/Area	$3/in^2$	$3/in^2$	$3/in^2$
Minimum Spacing	1X	1X	1X

Negative or Fusion Weld Repairs

	Surface 1	Surface 2	Surface 3
Surface Name	Articulating/Polished Surface	Porous Coated Surface	Edges/Polished Surface
Maximum Depth	NA	0.010	0.005
Maximum Length	NA	0.500	0.375
Maximum Qty/Area	NA	$3/in^2$	$3/in^2$
Minimum Spacing	NA	1X	1X

Notes:

1. Lengths may be assumed to be the diameter of the circle that encompasses the discontinuity.
2. Depth and height of a discontinuity should be measured or referenced from the defined profile of the cast part.
3. All dimensions are in inches.

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Specification	Revision	Issue Date	Originator: Engineering
S-007	C	8/16/99	Michael J. Pappas

Appendix A

Specification	Revision	Issue Date	Originator: Engineering
S-008	A	06/20/97	Michael J. Pappas

ENDOTEC, INC.

29 Valley Street, South Orange, New Jersey 07079

SPECIFICATION # S-008

Specification Title: Radiographic Inspection for Ti-6Al-4V Alloy Castings for Surgical Implants

1. SCOPE

1.1 This specification defines the radiographic inspection acceptance criteria for Ti-6Al-4V alloy castings to be used in the manufacture of surgical implants.

2. APPLICABLE DOCUMENTS

2.1 ASTM Standards:

- E 94 Standard Practice for Radiography of Cast Metallic Surgical Implants
- E 446 Standard Reference Radiographs of Investment Steel Castings of Aerospace Quality
- E 1316 Standard Terminology
- E 1742 Standard Practice for Personnel Qualification for Non-Destructive Testing
- E 1735 Standard Test Method

2.2 SNT-TC-1A Supplement D Recommended Practice, Personnel Certification and Qualification in Non-Destructive Testing

2.3 MIL-I-45208A Specification of General Requirements for a Quality Control Program

2.4 MIL-I-6866B Specification for Ti-6Al-4V Alloy Castings for Surgical Implants

2.5 FDA Guidelines on Good Manufacturing Practices

3. QUALIFIED PERSONNEL

3.1 Personnel performing radiographic inspection for cast part inspection shall have vision rating

3.1.1 Vision (Jaeger) 20/25 or better

3.1.2 Vision (Jaeger) Type 2 at 14 inches or better

3.1.3 Passing (4 of 6 responses on Titmus test)

3.2 Personnel performing radiographic inspection shall be qualified in accordance with MIL STD 410 requirement D.

4. CASTINGS

4.1 Castings shall be processed in accordance with ASTM F629.

4.2 Radiographic inspection of cast parts shall be performed after all thermal processing is completed.

4.3 Castings shall be in accordance with the following guidelines:

4.3.1 Discontinuities not permitted in cast parts. Discontinuities with diameters of less than shall be acceptable if this guideline exceeds the acceptance standards of ASTM E

5. REVISIONS

5.1 Shall maintain a revision program such as defined in ASQC or equivalent.

6. DOCUMENTATION

6.1 Shall perform and verify all tests and processes required by ASTM F629 and this specification.

6.2 Certificate of conformance to the above shall contain, but not be limited to:

6.2.1 Rating of cast parts in accordance with ASTM F629

6.2.2 Acceptance of cast parts in accordance with S-008

6.2.3 Serial cast parts

Procedure	Revision	Issue Date	Originator : Engineering
S-010	00	10/4/95	Michael J. Pappas

ENDOTEC, INC.

20 Valley Street, South Orange , New Jersey 07079

SPECIFICATION # S-010

Specification Title: **Material, Process, And Inspection Procedure For Porous Coated Titanium Orthopedic Implants.**

1.0 SCOPE

1.1 This specification describes the general process, quality control requirements and inspection criteria for the porous coating of surgical prostheses. This specification shall apply when referenced on engineering drawings process routers and purchase orders.

2.0 APPLICABLE DOCUMENTS

2.1 Specification for General Requirements for a Quality Program.

2.2 F565 Practice for the Care and Handling of Orthopedic Implants and Instruments.

2.3 Specification for Ti-6Al-4V ELI alloy for Surgical Implant Applications.

2.4 Specification for Unalloyed Titanium for Surgical Implants.

2.5 F1108 Specification for Ti-6Al-4V alloy Castings for Surgical Implants.

2.6 Solution Treatment and Aging of Titanium Implants.

2.7 Specification for Good Manufacturing Practices.

3.0 DEFINITIONS

3.1 Orthopedic Implant is defined by F565 as a device introduced by surgically penetrating skin or mucosa of the body with the intention that it remain after the body leaving surgery.

4.0 MATERIAL

4.1 The composition of materials used for this porous coating process shall meet the requirements of

4.2 The substrate shall be essentially symmetrical, having a bright, smooth, surface finish and be free from any material contamination.

Procedure	Revision	Issue Date	Originator : Engineering
S-010	00	10/4/95	Michael J. Pappas

5.2. Powder shall be screened to the USA Sieve Series -45 to +60 mesh.

6. PROCESS / PROCEDURE DEFINITION

6.1. The implants shall be fixtured and properly identified in a vacuum chamber as per vendor customary practices.

6.2. Sintering shall be conducted in vacuum, or other suitable protective atmosphere, so as to assure that the resulting product is free of oxides, discoloration, or other evidence of contamination.

6.3. The coating thickness shall be specified by engineering drawing or purchase order agreement. Such thickness shall be specified as the number of layers of beads, with a corresponding dimensional thickness between 0.25 to 0.33 mm per layer.

6.4. Post sintering heat treatment shall be performed as per S-003. Such heat treatment shall be considered as a required and necessary secondary process to the sintering.

7. QUALITY ASSURANCE PROVISIONS

7.1. Vendor is to comply with all quality assurance provisions of this document and ASTM.

7.2. Vendor performing the sintering process shall supply all test samples required for post heat treatment mechanical and metallographic tests.

7.3. The coating spheres shall be clean and bright. They shall be free of any foreign matter or contamination. The coating shall be free of loose particles or particles which could be dislodged in ordinary handling.

7.4. Pore size shall be in the range of 150 to 500 µm, with an average of 325µm. Porosity percentage shall be from 30% to 40%.

7.5. Shear testing of the porous coating shall be performed per ASTM F-1147. The minimum bond strength of the porous coating shall be greater than 3000psi.

7.6. After sintering and heat treatment, the composition of both the powder particles and the substrate shall conform to ASTM F-67 and ASTM F136 respectively.

7.7. After sintering and heat treatment, the substrate must conform to the mechanical property requirements of ASTM F-136. Mechanical properties shall be determined on uncoated specimens of ASTM F-136 material processed through the porous coating sintering and heat treatment cycle.

8. [illegible] VISUAL INSPECTION

8.1. The coating shall be inspected by means of a 30-power magnifying eyeloop for minimum necking and 90% connectivity.

Necking is hereby defined as the amount of fusion between porous coating beads, expressed as the diameter of the beads (figure

Connectivity is hereby defined as having connection between beads (on the [illegible] places.

Procedure	Revision	Issue Date	Originator : Engineering
[illegible]	00	10/4/95	Michael J. Pappas

D T

T- 0.25D
Figure 1

REPORTING AND DOCUMENTATION

The Vendor shall provide certification that shall include but not limited to the following:

- Reference to this specification and statement of compliance.
- Vendor heat treatment Lot Number.
- Purchase Order number.
- Implants processed by Lot Number.
- Heat treatment tension test results.
- Cracking inspection results.

[illegible] test specimens shall be returned with the implants.

The vendor shall retain the process and test records in perpetuity. If the vendor is unable to maintain the retention requirement such records shall be transferred to Endotec Inc.

The vendor shall provide evidence of a quality system as defined in ISO 9002 or equivalent. Such evidence may include, but not limited to, records of calibration and NIST traceability of all control and monitoring devices used in this process.

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Specification	Revision	Issue Date	Originator: Engineering
0011	C	11/1/99	Michael J. Pappas

ENDOTEC, INC.

20 Valley Street, South Orange, New Jersey 07079

SPECIFICATION # S-011

Specification Title: Standard Practice and Process Specification for Ultracoat® on Orthopedic Implants

1. SCOPE

1.1. This specification applies to the general process and quality control requirements of the application of Titanium Nitride on F136 and F1108 implants with and/or without articulating surfaces. This specification shall be applied in the following order of precedence when referenced on 1)-purchase orders, 2) process routers, 3) engineering drawings.

2. PURPOSE

2.1. This specification defines general and minimum requirements for surface characteristics, method of surface preparation and practice for the application of UltraCoat® TiN on orthopedic implants with and /or without articulating polished surfaces.

3. APPLICABLE DOCUMENTS

The applicable issue shall be the issue in effect at the time of processing.

3.1. ISO 9001 Specification of General Requirements for a Quality Control Program.

3.2. ASTM-F565 Practice for the Care and Handling of Orthopedic Implants and Instruments.

3.3. ASTM-F136 Specification for Ti-6Al-4V ELI alloy for Surgical Implant Applications.

3.4. ASTM-F67 Specification for Unalloyed Titanium for Surgical Implants.

3.5. ASTM-F1108 Specification for Ti-6Al-4V alloy Castings for Surgical Implants.

3.6. S-010 Material, Process, and Inspection Procedure, Porous Coated Titanium Prostheses.

3.7. S-016 Specification for Good Manufacturing Practices.

3.8. S-013 Process and Quality Control Requirements for Polishing Orthopedic Implants.

3.9. S-015 Process and Quality Control Requirements for Glass Bead Blast Finish on Orthopedic Implants.

3.10. ISO 9001 Quality Systems-Model for Quality Assurance in Design, Development, Production, Installation, and Servicing.

4. DEFINITIONS

4.1. Orthopedic Implant, As defined by F565 is a device introduced by surgically penetrating the skin or mucosa of the body with the intention that it remain within the

ENDOTEC	Specification	Revision	Issue Date	Originator: Engineering
	0011	C	11/1/99	Michael J. Pappas

body following surgery. In addition these Implants shall be manufactured from F136 or F1108 base alloy and may or may not have porous coated areas per S-010.

4.2. **Coating Facility**. The administrative entity and location where the actual coating is applied. This may be a contracted vendor or an Endotec departmental entity.

5. QUALIFICATIONS OF INSPECTION PERSONNEL

5.1. All inspectors shall have a minimum vision rating in one eye as follows:
- 5.1.1. Near vision: Titmus Vision Tester 20/25 or better
- 5.1.2. Near vision acuity: Jaeger Type 2 at 14 inches or better
- 5.1.3. Color vision: Average(4 of 6 responses on Titmus test)

6. PROCESS/PROCEDURE DEFINITION

6.1. **Pre coat inspection and handling:**
- 6.1.1. All components shall be visually inspected by the TiN facility for any visible defects such as surface damage or poor surface condition.
- 6.1.2. All components shall be handled with gloves in a non-destructive contact manner to avoid any marking or abrasion by other implants, contact materials and/or fixturing.
- 6.1.3. Implants in an unacceptable incoming condition shall be segregated and the quality assurance manager of Endotec shall be contacted for instructions as to their disposition.
- 6.1.4. All porous coated implants shall be protected at all times from all solid particulate contaminants such as fibers, blast or machining media and dust.

6.2. **Surface cleaning**
- 6.2.1. Where required, the coating facility may at the permission of, or as prescribed by the purchasing documentation employ final polishing or cleaning methods to free the implant articulating surface of residual contaminants and to restore surface brilliance.
- 6.2.2. The Implants shall be free of contaminants prior to coating application. The TiN facility shall perform all cleaning processes so as to remove all contaminants visible at 2X or lower magnification. The cleaning process shall include but is not limited to the following sequence of operations:
  - 6.2.2.1. Hot immersion degrease or equivalent. The temperature shall be within the 105° F to 130° F for a minimum of 15 minutes.
  - 6.2.2.2. Hot Alkaline Detergent Ultrasonic bath. The temperature shall be within the 105° F to 130° F for a minimum of 15 minutes.
  - 6.2.2.3. Spray rinse.
  - 6.2.2.4. Multiple stage deionized or distilled water immersion rinse.
  - 6.2.2.5. Vapor / Hot air or Equivalent Drying.

[illegible] during cleaning and prior to FINAL drying shall the implant surface be allowed to dry, [illegible] of the cleaning baths shall remain to an absolute minimum. This is to minimize the [illegible] salts by the drying cleaning liquids.

Specification	Revision	Issue Date	Originator	Engineering
0011	C	11/1/99	Michael	Pappas

6.3. Coating

6.3.1. All masking requirements shall be specified by the purchase document or engineering drawing. All internal cavities are not expected to be coated, and that a transitional area is expected from internal to external surfaces. This shall not be considered masking, as it is inherent in the line of sight characteristics of the process.

6.3.2. All Implants shall be coated with UltraCoat® TiN by Physical Vapor Deposition.

6.3.2.1. The coating cycle temperature shall not be less than 750°F or greater than 1000°F.

6.3.2.2. Class 1 to Class 4 surfaces shall be exposed to an in chamber surface cleaning (Conditioning) process for a net minimum of ten (10) minutes for each surface. Longer time exposure may be necessary for complex geometries and exposure shall be such that the equivalent minimum cleaning is attained. Thus longer conditioning is permitted as necessary so as to attain an adequately clean surface.

6.3.2.3. Macro and micro particles shall be minimized by meticulous methods such as high current arc control and other methods at the discretion of the coating facility. The presence or evidence of such particle coating in visible voids, or the loss of surface brilliance on the post coated surfaces, shall constitute grounds for final product rejection.

6.3.3. Coating thickness distribution shall meet the thickness requirements specified by purchase order, engineering documents. Coating evaporation sources shall be adjusted by the coating facility so as to achieve the specified thickness.

6.3.3.1. Fixturing and orientation of parts in the chamber shall be such that the minimum thickness requirements and distribution are achieved by purchase order, the appropriate engineering documents.

6.3.3.2. The coating thickness shall be determined by a test coupon inserted with every coating cycle in the vicinity of the implants and mounted to the exterior circumference of the fixture. The coating thickness of the test coupon shall be measured and recorded.

6.3.3.3. Thickness correlation factors between implant and test coupon coating thickness shall be established and used to compute the expected TiN thickness on implants as specified. Where available, direct non-destructive coating thickness measurements may be used to replace computed correlation methods. All correlation factors shall be related to chamber size, fixturing, part configuration, and cycle parameters.

6.4. Post Processes

6.4.1. All surfaces indicated as polished shall be post coating cleaned and buffed to the surface finish of the surface prior to coating. All macro and micro particles shall be removed or polished to a finish as specified by the engineering documents. In no case polishing shall expose any areas of substandard coating and shall be cause for rejection at final inspection.

Specification	Revision	Issue Date	Originator, Engineering
0011	C	11/1/99	Michael J. Pappas

6.4.2. All Implants shall be subjected to a minimum of fifteen (15) minutes of ultrasonic soak. The ultrasonic environment shall be at a minimum of 2.4W at 25khz to 50khz and 100°F to 150°F. This shall be referred to as the Ultrasonic Adhesion test and shall be performed after polishing and prior to final inspection.

7. INSPECTION PROCEDURES AND QUALITY CONTROL

7.1. Receiving

7.1.1. All Implants shall be inspected for any visible surface defects or poor surface condition.

7.1.2. All implant surfaces shall be inspected for any surface and / or particulate contamination.

7.2. Final Inspection

7.2.1. Following ultrasonic exposure, all parts shall be inspected for surface and coating defects. Defects shall be marked and classified as:

7.2.1.1. VOID: Areas void of coating where the substrate material is visible. This shall include all areas of discoloration.

7.2.1.2. ARC: Areas of arcing whether covered with fluorescent coating or not. This shall include linear and circular micro arcs.

7.2.1.3. MASK: Uneven or incorrect masking.

7.2.1.4. DAMAGE: Surface damage as a result of [illegible] misuse. All visible scratches shall be included in this classification.

7.2.1.5. POLISH: Substandard post coat polishing of the implant.

8. [illegible] AND DOCUMENTATION

8.1. All Implants shall be processed according to S016.

8.2. At the time of shipments the coating facility shall provide a certificate of conformance to this specification. Such certificate shall contain , but not be limited to:

8.2.1. Coating cycle Number.

8.2.2. Implant Lot Number.

8.2.3. Coating cycle date.

8.2.4. Coating thickness (a) as computed, (b) as correlated on specific implant type.

8.2.5. A minimum of 1/3 of the test coupon attached.

8.2.6. Statement of compliance to this specification as it applies to the particular parts described.

8.2.7. A copy of the inspection reports attached.

8.3. The coating facility shall retain the process and test records in their entirety. Where the facility is unable to maintain the retention requirement such records shall be transferred to Endotec for retention.

8.4. Upon request, the vendor shall provide evidence of a quality program as defined in ISO 9001 or equivalent.

Specification	Revision	Issue Date	Originator: Engineering
0011	C	11/1/99	Michael J. Parpas

9. REJECTION & REWORK

9.1. All implants, rejected at the receiving stage shall be segregated and Endotec's quality assurance manager shall be contacted for instructions as to their disposition.

9.2. Implants may NOT be stripped and recoated unless specified by the purchasing documentation or engineering documentation. The coating thickness requirement for recoated Implants shall apply, and shall be considered to be the thickness of the top-coating layer. Implants may not be recoated by the Coating facility without an engineering review and approval by Endotec.

Class Ledger: **Surface classification for TiN thickness and quality characteristics.**

Surface Identification	Surface Finish
Polish or Polished	0.10 microns
Articulating	0.05 microns
Articulating Spherical	0.025 microns

Table 1. Surface Finish Definition

Articulating: as defined on engineering drawings
No Voids Larger than 0.005", one per 1 sq. in.
No Ares Larger than 0.005", one per 1 sq. in.
No Discoloration
Thickness 3 to 5 Microns

Articulating Spherical: as defined on engineering drawings
No Voids
No Ares
No Discoloration
Thickness 3 to 5 Microns

Blending: as defined on engineering drawings and ALL radii 250 microns from articulating to non articulating surfaces
No Voids Larger than 0.008", one per ¼ sq. in.
No Ares Larger than 0.008", one per ¼ sq. in.
No Discoloration
Thickness 2 to 5 Microns

Surfaces defined as polished or classified on engineering drawings
No Voids Larger than .016", one per ¼ sq. in.
Ares to 0.016", one per 1/4 sq. in.
No Discoloration
Thickness 2 to 5 Microns

Surfaces not defined as polished (Machined, glass beaded, sand blasted, etc.), and with radius of .016" or smaller. All porous coated surfaces
No Voids Larger than .031" one per 1/4 sq. in.
Ares to Max. 0.250, one per 1 sq. in.
No Discoloration

Specification	Revision	Issue Date	Originator / Engineering
0011	C	11/1/99	Michael J. Pappas

Thickness up to 8 Microns (No visible substrate)

MASK: Masking line (Discoloration) 0.031 wide allowed at the border created to uncoated surfaces as surface transitions from internal to external surfaces where the internal opening is smaller than 0.150" diameter.

Polishing Flaws-where macro particles are integrated within the coating structure their subsequent post coat polishing may leave visual surface wavyness. Such features are not permitted on class 1 surfaces. On all other surface classes such features are allowed up to .01" diameter at 1 per 3 square inch.

Procedure	Revision	Issue Date	Originator : Engineering
S-012	00	10/4/95	Michael J. Pappas

ENDOTEC, INC.

20 Valley Street, South Orange , New Jersey 07079

SPECIFICATION # S-012

Specification Title: **Standard Practice and Process specification for UltraCoat ®on Stainless Steel Tools**

1. SCOPE

1.1. This specification covers the minimum requirements for surface characteristics, method of surface preparation and practice for the application of UltraCoat TiN on surgical instruments and Implants.

2. APPLICABLE DOCUMENTS

2.1. ASTM F899 Standard Specification for Stainless Steel, Billet , Bar and Wire for surgical Instruments.

3. DEFINITIONS

3.1. Orthopedic Instrument is defined as any device used during a surgical procedure.

4. PROCESS / PROCEDURE DEFINITION

4.1. **Pre coat Inspection.**

4.1.1. All components shall be visually inspected by the TiN vendor for any visible defects such as surface damage or poor surface condition.

4.1.2. All components shall be handled in a non destructive contact manner to avoid any marking or abrasion by other instruments or fixturing.

4.1.3. Instruments in an unacceptable incoming condition shall be segregated and the quality assurance manager of the customer shall be contacted for instructions as to their disposition.

4.2. **Surface cleaning.**

4.2.1. The instruments shall be free of any contaminants prior to coating. The TiN vendor shall perform all cleaning processes so as to remove all contaminants. The cleaning process shall include but is not limited to:

4.2.1.1. Hot degrease or equivalent.

4.2.1.2. Hot Alkaline Detergent, Ultrasonic bath for a minimum of five minutes.

4.2.1.3. De ionized or distilled water soak and rinse.

4.2.1.4. spray rinse

4.2.1.5. Vapor Dry or Equivalent.

Procedure	Revision	Issue Date	Originator : Engineering
S-012	00	10/4/95	Michael J. Pappas

4.2.2. Where required, instruments may at the permission of, or as prescribed by the purchasing documentation employ blast methods to free instrument surface of residual contaminants.

4.3. Coating

4.3.1. All masking requirements shall be specified by the purchasing document or engineering drawing referring to this specification.

4.3.2. All instruments shall be coated with TiN using the UltraCoat Physical Vapor. Deposition as described herein and S-011.

4.3.3. Coating thickness shall be at 2 to 4 microns on all cutting surfaces, or as otherwise specified by purchase order and engineering documents. Coating time parameters shall be adjusted by the coater to achieve the specified thickness.

4.3.3.1. Fixturing and orientation of parts in the chamber shall be as specified by the appropriate engineering or process drawing

4.3.3.2. The coating thickness shall be determined by a test coupon inserted with every coating cycle at the vicinity of the instruments and oriented to the exterior circumference of the fixture. The ball crater method shall be used to establish the thickness. Coating thickness correlation factors to the coupon shall be as specified by the appropriate engineering or process drawing

4.4. Post Coat Processes

4.4.1. All instruments shall be subjected to a minimum of five minutes of ultrasonic soak. The ultrasonic Environment shall be at 2 kW 20khz and 120°F .

INSPECTION PROCEDURES

5.1. Receiving

5.1.1. All instruments shall be inspected for any visible surface defects or poor surface condition.

5.2. Final Inspection

5.2.1.1. Following ultrasonic exposure , all parts shall be inspected for surface defects resulting from:

5.2.1.2. Areas void of coating larger than .005"

5.2.1.3. Areas of arcing whether covered with subsequent coating or not of combined length and width larger than .125".

5.2.1.4. Areas of discoloration of combined length and width larger than .125".

5.2.1.5. Uneven or incorrect masking line location.

5.2.1.6. Surface damage as a result of mechanical misuse of the instrument.

REPORTING AND DOCUMENTATION

Procedure	Revision	Issue Date	Originator : Engineering
S-012	00	10/4/95	Michael J. Pappas

6.1. All instruments shall be processed according to S-016.

6.2. At the time of shipments the coater shall provide a certificate of conformance to this specification. Such certificate shall contain, but not be limited to :

6.2.1. Coating cycle. Number and date.

6.2.2. Ultrasonic exposure results.

6.2.3. Coating thickness as required by this specification.

6.2.4. A minimum of 1/3 of the test coupon attached.

6.3. The vendor shall retain the process and test records in perpetuity. Where the vendor is unable to maintain the retention requirement such records shall be transferred to Endotec for retention.

6.4. Upon request, the vendor shall provide evidence of a quality program as defined in ASQC C1-1985, or equivalent. Such evidence may include, but not be limited to, certification of calibration and NIST traceability of all controlling and monitoring equipment used in this process.

REJECTION & REWORK

7.1. All instruments, unless otherwise specified by the purchasing documentation or engineering specification, may be recoated. The coating thickness requirement of recoated instruments shall be the cumulative net of each coating cycle. Instruments may be recoated three times without the need for engineering review and approval.

Procedure	Revision	Issue Date	Originator : Engineering
S-013	C	3/8/00	*Michael J. Pappas*

ENDOTEC, INC.

20 Valley Street, South Orange, New Jersey 07079

SPECIFICATION # S-013

Specification Title: **General Process and Quality Control Requirements and Inspection Criteria For The Polishing Of Orthopedic Implants.**

1. SCOPE

1.1. This specification applies to the general process and quality control requirements and inspection criteria for the polishing of orthopedic implants.

2. PURPOSE

2.1. This specification specifies general and minimum requirements for surface characteristics, method of surface preparation and inspection criteria for orthopedic implants with articulating polished surfaces. It is applicable when referenced on engineering drawings, process sheets and/or purchase orders.

3. APPLICABLE DOCUMENTS

3.1. [illegible] Specification of General Requirements for a Quality Control Program.

3.2. [illegible] Practice for the Care and Handling of Orthopedic Implants and Instruments.

3.3. [illegible] Specification for Titanium 6Al-4V ELI Alloy for Surgical Implant Applications.

3.4. [illegible] Specification for Unalloyed Titanium for Surgical Implants.

3.5. [illegible] Specification for Ti-6Al--V Alloy Castings for Surgical Implants.

3.6. [illegible] Certification & Qualification of Nondestructive Test Personnel.

3.7. [illegible] Supplement D Recommended Practice, Personnel Certification and

3.8. [illegible] Non-Destructive Testing

4. DEFINITIONS

4.1. [illegible] defined by F565 as a device introduced by surgically penetrating the skin or mucosa of the [illegible] remain within the body following surgery.

4.2. [illegible] is defined on a drawing or document requiring polishing.

4.3. [illegible] face is defined as a polished surface that would potentially have bearing articulation.

4.4. [illegible] face is defined on a drawing or document as "spherical surface"

5. QUALIFICATIONS OF INSPECTION PERSONNEL

5.1. [illegible] shall have a minimum vision rating in one eye as follows.

Procedure	Revision	Issue Date	Originator : Engineering
S-013	C	3/8/00	*Michael J. Pappas*

5.2. Near vision: Titmus Vision Tester 20/25 or better

5.3. Near vision acuity: Jaeger Type 2 at 14 inches or better

5.4. Color vision: Average(4 of 6 responses on Titmus test)

6. PROCESS / PROCEDURE DEFINITION

6.1. **Pre polish surface:**

6.1.1. The surface finish of all components prior to polishing shall be ground or machined to an RMS. of 16 micro inches or better. All components shall be visually inspected for any defects such as surface damage or poor surface condition.

6.1.2. All components shall be inspected for dimensional conformance to the engineering drawing requirements at the pre-polished state.

6.1.3. Implants in an unacceptable pre-polished condition shall be segregated and the quality assurance manager shall be contacted for instructions as to their disposition

6.1.4. All porous coated implants shall be protected from all solid particulate contaminants such as machining media, abrasives and dust. Temperature and solubility characteristics of masking media are to be considered so as not to compromise their in process performance and their later integral removal from implants.

6.2. **Polishing and Buffing :**

6.2.1. All implant surfaces requiring polishing per this specification and as otherwise specified by the governing drawings shall be polished to a final surface finish as defined in table 1. Such polishing shall be achieved by the successive use of finer media. The material removal rate of the process shall be established and appropriate allowances shall be made at the pre-polished dimensional state. It is recommended that single step processes be avoided unless reliable dimensional control exists.

Surface Identification	Surface Finish
Polish or Polished	0.10 microns
Articulating	0.05 microns
Articulating Spherical	0.025 microns

Table 1. Surface Finish Definition

6.2.2. The implants shall be buffed at the polished state to introduce a high reflective brilliance to the polished surfaces. This process shall remove all surface characteristics less than the RMS specified in table 1

6.2.3. All porous coated implants shall be protected from all liquid and particulate contaminants such as polishing media, abrasives and dust. Temperature and solubility characteristics of masking media are to be considered so as not to compromise their in process performance and their later integral removal from implants.

6.2.4. All polished surfaces coated with TiN shall be repolished as necessary to restore the surface finish of the surface according to specification S-011. In addition such polishing shall expose all and any areas of substandard coating.

6.2.5. All TiN coated implants shall be subjected to a minimum of five minutes of post polish ultrasonic soak. The ultrasonic Environment shall be at a minimum of 100kW/m^3 and a minimum of 40khz and 100°F. This shall be referred to as the ultrasonic adhesion test.

Procedure	Revision	Issue Date	Originator : Engineering
S-013	C	3/8/00	*Michael J. Pappas*

7.1. **Receiving:**

7.1.1. All implants shall be inspected by the polishing facility for any visible surface defects or poor surface condition.

7.2. **Final Inspection:**

7.2.1. All implants shall be visually inspected under natural light to verify the absence of all surface characteristics visible to the unaided eye such as scratches and haziness.

7.2.2. Surface damage as a result of mechanical misuse or substandard post coat polishing of the Implant.

7.2.3. The implant surface finish shall be copared to known surface finish masters for color and uniformity. Such comparison may be performed with unaided eye or other means.

8. REPORTING AND DOCUMENTATION

8.1. All implants shall be processed according to S016.

8.2. At the time of shipment the polishing facility shall provide a certificate of conformance to this specification. Such certificate shall contain, but not be limited to :
- Implant Lot Number quantities and date.

9. REJECTION & REWORK

9.1. Unless otherwise specified by the purchasing documentation or engineering specification, all parts are rejected. All necessary repolishing may be performed after authorization by the QA manager for dimensional integrity.

Procedure	Revision	Issue Date	Originator : Engineering
S-014	00	10/4/95	Michael J. Pappas

ENDOTEC, INC.

20 Valley Street, South Orange , New Jersey 07079

SPECIFICATION # S-014

Specification Title: **Specification For The General Process And Quality Control Requirements And Inspection Criteria For The Sand Blast Surface Finish On Orthopedic Products.**

1. SCOPE

1.1. This specification applies to the general process and quality control requirements and inspection criteria for the sand blasting of finished surfaces of orthopedic implants and instrumentation.

2. PURPOSE

2.1. This specification specifies general and minimum requirements for surface characteristics, method of surface preparation and inspection criteria for orthopedic implants and instruments specified to have a sand blast surface finish. This shall apply when referenced on engineering drawings, process routers and or purchase orders.

3. APPLICABLE DOCUMENTS

3.1. ASQC-C1 Specification of General Requirements for a Quality Control Program.

3.2. ASTM-F565 Practice for the Care and Handling of Orthopedic Implants and Instruments.

3.3. ASTM-F136 specification for Titanium 6Al4V ELI Alloy for Surgical Implant Applications.

3.4. ASTM-F67 Specification for Unalloyed Titanium for Surgical Implants.

3.5. ASTM-F1108 Specification for Ti6Al4V Alloy Castings for Surgical Implants.

3.6. ASTM-F799-87 Standard specification for thermomechanically processed cobalt-chromium-molybdenum alloy for surgical implants.

4. DEFINITIONS

4.1. Orthopedic Implant and instruments are as defined by F565 .

5. PROCESS / PROCEDURE DEFINITION

5.1. Pre blast surface:

5.1.1. The surface finish of all components prior to sand blasting shall be ground or machined to an RMS. of 16 micro inches or better. All components shall be visually inspected for any defects such as surface damage or poor surface condition.

5.1.2. All components shall be inspected for dimensional conformance to the engineering drawing requirements at the pre- polished state.

ENDOTEC	Procedure	Revision	Issue Date	Originator : Engineering
	S-014	00	10/4/95	Michael J. Pappas

5.1.3. All porous coated implants shall be protected from all solid particulate contaminants such as machining media, abrasives and dust. Temperature and solubility characteristics of masking media are to be considered so as not to compromise their in process performance and their later integral removal from implants.

5.2. **Sand blasting** :

5.2.1. The parts shall be sand blasted by Aluminum Oxide blast media sieve size 60-80.

5.2.2. All parts shall be subjected to a minimum of five minutes of post blast ultrasonic wash. The ultrasonic Environment shall be at 2 kW 20khz to 2kW 50khz and 100°F 120°F.

6. INSPECTION REQUIREMENTS

6.1. **Receiving:**

6.1.1. All parts shall be inspected by the finishing facility for any visible surface defects or poor surface condition.

6.2. **Final Inspection:**

6.2.1. All implants shall be visually inspected under natural light to verify the uniformity of surface characteristics as a result of this process and visible to the unaided eye .

7. REPORTING AND DOCUMENTATION

7.1. All implants shall be processed according to S-016.

8. REJECTION & REWORK

8.1. All parts, unless otherwise specified by the purchasing documentation or engineering specification, may be reworked. All abrasive or machining operations necessary to repair any damage may be performed after authorization by the QA manager for part dimensional integrity.

Procedure	Revision	Issue Date	Originator : Engineering
S-015	00	10/4/95	Michael J. Pappas

ENDOTEC, INC.

20 Valley Street, South Orange , New Jersey 07079

SPECIFICATION # S-015

Specification Title: **Specification For The General Process And Quality Control Requirements And Inspection Criteria For The Glass Bead Blast Surface Finish On Orthopedic Products.**

1. SCOPE

1.1. This specification applies to the general process and quality control requirements and inspection criteria for the glass bead blasting of finished surfaces of orthopedic implants and instrumentation.

2. PURPOSE

2.1. This specification specifies general and minimum requirements for surface characteristics, method of surface preparation and inspection criteria for orthopedic implants and instruments specified to have a glass bead blast surface finish. This shall apply when referenced on engineering drawings , process routers and or purchase orders.

3. APPLICABLE DOCUMENTS

3.1. ASQC-C1 Specification of General Requirements for a Quality Control Program.

3.2. ASTM-F565 Practice for the Care and Handling of Orthopedic Implants and Instruments.

3.3. ASTM-F136 Specification for Titanium 6Al-4V ELI Alloy for Surgical Implant Applications.

3.4. ASTM-F67 Specification for Unalloyed Titanium for Surgical Implants.

3.5. ASTM-F1108 Specification for Ti-6Al-4V Alloy Castings for Surgical Implants.

3.6. ASTM-F799-87 Standard specification for thermomechanically processed cobalt-chromium-molybdenum alloy for surgical implants.

4. DEFINITIONS

4.1. Orthopedic Implant and instruments are as defined by F565 .

5. PROCESS / PROCEDURE DEFINITION

5.1. **Pre blast surface:**

5.1.1. The surface finish of all components prior to glass bead blasting shall be ground or machined to an RMS. of 16 micro inches or better. All components shall be visually inspected for any defects such as surface damage or poor surface condition.

5.1.2. All components shall be inspected for dimensional conformance to the engineering drawing requirements at the pre- polished state.

5.1.3. All porous coated implants shall be protected from all solid particulate contaminants such as machining media, abrasives and dust. Temperature and solubility characteristics of masking

ENDOTEC	Procedure	Revision	Issue Date	Originator : Engineering
	S-015	00	10/4/95	Michael J. Pappas

media are to be considered so as not to compromise their in process performance and their later integral removal from implants.

5.2. **Glass bead blasting** :

5.2.1. The parts shall be bead blasted by glass beads sieve size 140-270.

5.2.2. All TiN coated implants shall be subjected to a minimum of five minutes of post polish ultrasonic wash. The ultrasonic Environment shall be at 2 kW 20khz to 2kW 50khz and 100°F 120°F.

6. INSPECTION REQUIREMENTS

6.1. **Receiving:**

6.1.1. All parts shall be inspected by the finishing facility for any visible surface defects or poor surface condition.

6.2. **Final Inspection:**

6.2.1. All implants shall be visually inspected under natural light to verify the uniformity of surface characteristics as a result of this process and visible to the unaided eye .

7. REPORTING AND DOCUMENTATION

7.1. All Implants shall be processed according to S-016.

8. REJECTION & REWORK

8.1. All parts, unless otherwise specified by the purchasing documentation or engineering specification, may be reworked. All abrasive or machining operations necessary to repair any damage may be performed after authorization by the QA manager for part dimensional integrity.

Specification	Revision	Issue Date	Originator/Quality Assurance
S-021	B	11/11/99	

Procedure	Revision	Issue Date	Originator : Engineering
S-022	B	8/5/99	*Mir Taher*

ENDOTEC, INC.

20 Valley Street, South Orange , New Jersey 07079

SPECIFICATION # S-022

Specification Title: **Requirements for The Validation and Routine Monitoring of Sterilization by Gaseous Ethylene Oxide.**

1. SCOPE

1.1. This specification describes the requirement for the development, validation, process control, and monitoring of the sterilization of medical devices using ethylene oxide.

2. PURPOSE

2.1. This specification shall provide the specification and quality requirements for the validation and routine sterilization of medical devices using ethylene oxide, and shall conform to ISO 11135, and Health Care industry standards. This specification shall be used and referenced on all purchase orders, travelers, etc..

3. APPLICABLE DOCUMENTS

3.1. ISO 9001 Quality Systems. Model for Quality Assurance in Design, Development, Production, Installation, and Servicing.

3.2. ISO 11135 Validation and Routine Control of Ethylene Oxide Sterilization

3.3. EN-46002 Quality System Requirements for Medical Devices.

3.4. AAMI Standards and Recommended Practices.

3.5. AAMI TIR 28 Process Validation for EtO Sterilization Microbiological Aspects

3.6. ISO TC 194/DIS1C993-7.2 EtO Sterilization Residuals.

4. DEFINITIONS

4.1. **Aeration.** Part of the sterilization process during which ethylene oxide is desorb from the medical device until predetermined levels are reached.

4.2. **Bioburden.** The total number of viable microbes on a packaged item or medical device prior to the sterilization processing.

4.3. **Commissioning.** Obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications and that it functions within predetermined limits when operated in accordance with operational instructions.

4.4. **Conditioning.** Treatment of product within the sterilization cycle, but prior to sterilant admission, to attain predetermined temperature and relative humidity throughout the sterilization load.

4.5. **D-value (decimal reduction value.** Time (expressed in miniciles) required to secure inactivation of 90% of a population of organisms under stated exposure conditions.

Procedure	Revision	Issue Date	Originator : Engineering
S-022	B	8/5/99	*Mir Taher*

4.6. **Exposure Time.** Time for which the sterilizing chamber is maintained at the specified temperature, sterilant concentration, pressure, and humidity.

4.7. **Inoculated carrier,** Piece of supporting material on which a defined number of specified microorganisms has been deposited.

4.8. **Performance Qualification,** Obtaining and documenting evidence that the equipment as commissioned will produce acceptable product when operated in accordance with the process specification.

4.9. **Preconditioning,** (See **Conditioning**)

4.10. **Process Challenge Device,** Object that simulates the worst case of conditions, as they are given by the sterilizing agent, in the items of the goods to be sterilized.

4.11. **Process Development,** Documented program of studies that is performed to define the sterilization process based upon the product/packaging loading pattern and/or equipment limitations.

4.12. **Process Qualification,** Obtaining and documenting evidence that the sterilization process will produce acceptable health care products.

4.13. **Product Compatability,** Ability of the sterilization cycle to achieve the intended results without a detrimental effect on the product.

4.14. **Product Qualification.** Obtaining and documenting evidence health care product will be acceptable for [illegible] after exposure to EtO.

4.15. **Sample.** The experimental unit that is either the whole medical device or an [illegible] portion thereof, [illegible] weight, volume, or surface area, chosen to represent the [illegible] validity.

4.16. **Sterile.** Condition of a medical device that is free from viable microorganisms.

4.17. **Sterility Assurance Level.** The expected probability of an item or unit being nonsterile after exposure to [illegible] sterilization process. SAL's range from 10^{-3} to 10^{-6} depending on product use.

4.18. **Sterility Assurance Level dose,** the dose in KGy required to achieve the desired SAL.

4.19. **Sterilizing Facility,** the place where sterilization and sterilization validation is performed, either in-[illegible] contract sterilizer.

4.20. **Validation,** Establishing documented evidence that provides a high degree of assurance that a specific [illegible] will consistently produce a product meeting its predetermined specifications and quality characteristics.

5. PROCEDURE VALIDATION

5.1. Validation shall be performed using method C, the Half cycle method of AAMI/ ANSI/ISO 11135 [illegible]. The validation shall include:

5.1.1. **Commissioning;**

5.1.2. **Performance Qualification,** Physical;

5.1.3. **Performance Qualification,** Microbiological;

5.1.4. **Certification of Validation;**

5.1.5. **Process Control and Monitoring;**

5.1.6. **Product Release from Sterilization.**

5.2. [illegible] shall be associated with demonstrating that the equipment conforms to specification [illegible] qualification, and demonstrating that acceptable product will be produced when the [illegible] is used in accordance with documented procedures. The Sterilizing Facility is

ENDOTEC	Procedure	Revision	Issue Date	Originator : Engineering
	S-022	B	8/5/99	*Mir Taher*

responsible for commissioning the equipment. They shall demonstrate that the equipment specifications for the preconditiong sterilization, and aeration equipment are met. The Contract Sterilizing Vendor shall also demonstrate documented evidence of calibration of all instrumentation for controlling the load condition, indicating, and recording the sterilization process. As part of preconditioning for temperature and humidity shall be monitored per ISO 11135 guidelines.

5.3. **Performance Qualification, Physical** Physical performance qualification shall be performed on the introduction of new product, significant changes to existing product in product design, packaging, sterilization load configuration or density, sterilization equipment, or process cycle. The effects of such changes on all stages of the sterilization including preconditioning and aeration should be determined. The Sterilizing Facility is responsible for performance qualification (physical) in accordance with ISO 11135 guidelines and shall furnish documentation as part of the validation revalidation reports. Performance qualification shall be performed in the chamber for both minimum and maximum load sizes during validation using the half cycle method. Temperature profiles of the sterilization load shall be determined for each loading pattern. The location of the probes throughout the sterilization load should be selected to determine the maximum temperature variation, and take into account hot or cold spots located during commissioning. Physical performance factors should be determined for the specified loading patterns in order to prepare the operating specification. These factors should include:

5.3.1. The depth and rate of attainment of vacuum;

5.3.2. The chamber leak rate (performed either under vacuum for sub-atmospheric cycles, or under vacuum and at pressure for super-atmospheric cycles.)

5.3.3. The pressure rise or injection of steam during the conditioning phase

5.3.4. The pressure rise and rate of attainment on admission of EtO and [illegible] of factors with [illegible] it is intended to monitor gas concentration.

5.3.5. The depth and rate of attainment of vacuum used to remove EtO.

5.3.6. The pressure rise and rate of attainment of pressure on admission of air.

5.4. **Performance Qualification, Microbiological** Microbiological performance qualification shall be [illegible] the introduction of new product, significant changes to existing product in product design, [illegible]ization load configuration or density, sterilization equipment, or process cycle. The [illegible] changes on all stages of the sterilization including preconditioning and aeration should be [illegible] The Sterilizing Facility is responsible for performance qualification (microbiological) in [illegible] in ISO 11135 guidelines and shall furnish documentation as part of their [illegible] validation reports. Since the number and resistance of microorganisms on any particular [illegible] sterilization is unknown, the efficiency of a sterilization cycle is demonstrated by [illegible] study to determine the naturally occurring bioburden on the product prior to sterilization vs. [illegible] (Biological Indicator) BI's. BI's shall be used with known microorganisms. The [illegible] the type of BI's to be used is the responsibility of the Sterilizing Facility and shall satisfy the [illegible] ISO 11135 and AAMI TIR guidelines. The resistance of these microorganisms shall be [illegible] in the sterilization cycle specification. If the naturally occurring bioburden or CFU's are [illegible] BI's should be placed in the part of the product that is most difficult to sterilize. If the [illegible] product is such that a BI cannot be accommodated, the product shall be inoculated with the [illegible] to provide a known number of viable spores. BI's shall be used and should be placed in [illegible] where sterilization conditions are the most difficult to achieve. Microbiological [illegible] qualification shall be carried out using Method C, the Half cycle method of [illegible] ISO 11135. This method involves determination of the minimum time of exposure to EtO, [illegible] process parameters, except time remaining constant, at which there are no survivors. Two [illegible] shall be performed to confirm the minimum time. Both should show no growth [illegible] The specified exposure time should be at least double the minimum time.

Procedure	Revision	Issue Date	Originator : Engineering
S-022	B	8/5/99	Mir Taher

5.5. **Certification of Validation** The validation report should include the following:

5.5.1. Details of product sterilized;

5.5.2. The specification of the Sterilizer;

5.5.3. The Commissioning data;

5.5.4. Records of performance qualification, physical and micrbiological;

5.5.5. The validation protocol;

5.5.6. The documented procedures used;

5.5.7. Documented operating procedures including process control limits.

5.6. **Maintenance of Calibration Procedures**

5.6.1. **Revalidation.** Revalidation shall be performed to confirm that inadvertent process changes have not been made, and to demonstrate that the original validation report remains valid. Revalidation will include elements of recommissioning and requalifications. If recommissioning or requalification detects a process change, the commissioning and performance qualification may need to be done again. Previous validation and revalidation results should be considered in establishing the revalidation protocol. Data from the revalidation should be compared with records of the original validation to confirm that the original performance has been retained. The Sterilizing Facility is responsible for developing the protocol and performing the revalidation per ISO 11135 guidelines.

5.7. **Routine Sterilization, Control and Release**

5.7.1. The routine EtO sterilization of a medical device is critical to ensure device sterility, safety, and effectiveness. Consistant operating conditions should be maintained and monitored, and control of the EtO sterilization process should be designated.

5.7.2. Data shall be recorded and retained for each sterilization cycle to demonstrate that the sterilization process specification has been met. The data should include the following:

5.7.2.1. Temperature within the sterilization load during preconditioning.

5.7.2.2. Time of commencement and removal of the sterilization load from preconditioning for each sterilization load.

5.7.2.3. Time of commencement of the sterilization cycle of each sterilization load.

5.7.2.4. Temperature within the sterilization load during the sterilization cycle.

5.7.2.5. Humidity during conditioning as determined by direct measurement.

5.7.2.6. Pressure in the chamber during the sterilization cycle.

5.7.2.7. Evidence that EtO has been admitted to the sterilization chamber.

5.7.2.8. Concentration of EtO in the chamber determined by analysis.

5.7.2.9. Exposure time.

5.7.2.10. Aeration time.

5.7.3. Besides these parameters, Biological Indicators (BI's) shall be used in glassine (placed with the samples) and placed in an area that is the most difficult to sterilize. When the sterilization cycle is complete, the BI's shall be removed from the glassine and sent for testing. Based on the BI's results, the lot shall be released. There shall not be any positives in the BI's testing. The Sterilizing Facility shall be responsible for proving the data as well as monitoring the sterilization process.

5.7.4. The other process parameters are by a sterilization and testing protocol developed by vendor and agreed upon by Endotec QA.

5.8. EtO Residuals

Procedure	Revision	Issue Date	Originator : Engineering
S-022	B	8/5/99	Mir Taher

5.8.1. EtO for sterilization of medical devices at acceptable residual levels prove no risk to the patient in normal product use, but any exposure of more them normal may cause or is known to exhibit a number of biological effects, and consideration should be given to EC (Ethylene Chlorohydrin) and EG (Ethylene Glycol) because of these potentially harmful effects.

5.8.2. The acceptable levels for Endotec devices shall be EtO 0.1mg/day ADD (averaged daily dose); EC 2mg/day ADD; and in ppm (parts per million) it is 100, 100, 1000 for EtO, EC and EG.

5.8.3. The method for determining EtO, EC, and EG residuals is the responsibility of the Sterilizing Facility and shall satisfy the requirement of ISO 10993.

5.8.4. For product lots processed 5 or less in a year, the release of product for Eto, EC, and EG residuals shall be performed for each individual lot, i.e. products without dissipation curve data.

5.8.5. For product lots processed 5 or more in a year, the release of product for Eto, EC, and EG residuals shall be performed per the procedure for product release using residual dissipation curves.

5.9. Reports

5.9.1. Validation Reports;

5.9.2. Revalidation Reports;

5.9.3. Routine Sterilization Reports.

Procedure	Revision	Issue Date	Originator : Engineering
S-023	C	7/14/04	*Mir Taher*

ENDOTEC, INC.

50 South Center Street, Orange, New Jersey 07050

SPECIFICATION # S-023

Specification Title: **Requirements for The Validation and Routine Monitoring of Sterilization by Gamma Radiation.**

1. SCOPE

1.1. This specification describes the requirement for the development, validation, process control, and monitoring of the sterilization of medical devices using gamma radiation.

2. PURPOSE

2.1. This specification shall provide the specification and quality requirements for the validation and routine sterilization of medical devices using gamma radiation, and shall conform to ISO and Health Care Industry standards. This specification shall be used and referenced on all purchase orders, travelers, etc..

3. APPLICABLE DOCUMENTS

3.1. EN ISO 9001 Quality Systems, Model for Quality Assurance in Design, Development, Production, Installation, and Servicing.

3.2. ANSI/AAMI/ISO **11137:1994/AI:2002** Requirements for Validation and Routine Control – Radiation Sterilization.

3.3. EN ISO 9001 Quality System Requirements for Medical Devices.

3.4. Vol. I AAMI Standards and Recommended Practices.

3.5. AAMI/TIR 27:**2001** Microbiological Methods for Gamma Irradiation Sterilization of Medical Devices.

3.6. ANSI/AAMI ST32 Guideline for gamma radiation sterilization

4. DEFINITIONS

4.1. **Absorbed dose**, the quantity of radiation energy absorbed per unit of mass. This quantity is usually referred to simply as "dose".

4.2. **Dosimeter**, a device or system having a reproducible, measureable response to radiation, which may be used to measure the quantity of absorbed dose in a given material.

5. PROCEDURE

5.1. **Sterilization and packaging**

5.1.1 All devices covered by this specification shall be sterilized and packaged in accordance with ANSI/AAMI/ISO/11137:1994/A1:2002 using a dose of 25kGy .

5.2. DOSE ESTABLISHMENT

5.2.1 Dose establishment for the dose of 25kGy shall be accomplished by the procedure of AAMI TIR27:2001

Procedure	Revision	Issue Date	Originator : Engineering
S-023	C	7/14/04	*Mir Taher*

5.2.2 **Processing Records.** The process specification should require the following information be recorded and reviewed by authorized individuals and maintained in the process documentation.

- 5.2.1.1. Incoming product count (number of boxes).
- 5.2.1.2. Product loading pattern in irradiation container.
- 5.2.1.3. Dosimeter placement in irradiation container.
- 5.2.1.4. Sterilization lot number.
- 5.2.1.5. Specified minimum and maximum dose radiation.
- 5.2.1.6. Sterilization date.
- 5.2.1.7. Dosimetric readings.

Procedure	Revision	Issue Date	Originator : Engineering
S-023	C	7/14/04	Mir Taher

ENDOTEC, INC.

50 South Center Street, Orange, New Jersey 07050

SPECIFICATION # S-023

Specification Title: **Requirements for The Validation and Routine Monitoring of Sterilization by Gamma Radiation.**

1. SCOPE

1.1. This specification describes the requirement for the development, validation, process control, and monitoring of the sterilization of medical devices using gamma radiation.

2. PURPOSE

2.1. This specification shall provide the specification and quality requirements for the validation and routine sterilization of medical devices using gamma radiation, and shall conform to ISO and Health Care Industry standards. This specification shall be used and referenced on all purchase orders, travelers, etc..

3. APPLICABLE DOCUMENTS

3.1. ISO 9001 Quality Systems, Model for Quality Assurance in Design, Development, Production, Installation, and Servicing.

3.2. ANSI/AAMI/ISO **11137:1994/AI:2002** Requirements for Validation and Routine Control – Radiation Sterilization.

3.3. CFR 820 Quality System Requirements for Medical Devices.

3.4. Vol. I AAMI Standards and Recommended Practices.

3.5. AAMI TIR **27:2001** Microbiological Methods for Gamma Irradiation Sterilization of Medical Devices.

3.6. ANSI/AAMI **ST32** Guideline for gamma radiation sterilization

4. DEFINITIONS

4.1. **Absorbed dose,** the quantity of radiation energy absorbed per unit of mass. This quantity is usually refered to simply as "dose".

4.2. **Dosimeter,** a device or system having a reproducible, measureable response to radiation, which may be used to measure the quantity of absorbed dose in a given material.

5. PROCEDURE

5.1. **Sterilization and packaging**

5.1.1 All devices covered by this specification shall be sterilized and packaged in accordance with ANSI/AAMI/ISO/111137:1994/A1:2002 using a dose of 25kGy .

5.2. DOSE ESTABLISHANTIATION

5.2.1 The substantiation for the dose of 25kGy shall be accomplished by the procedure of AAMI TIR27:2001

Procedure	Revision	Issue Date	Originator : Engineering
S-023	C	7/14/04	Mir Taher

5.2.2 **Processing Records.** The process specification should require the following information be recorded and reviewed by authorized individuals and maintained in the process documentation.

- 5.2.1.1. Incoming product count (number of boxes).
- 5.2.1.2. Product loading pattern in irradiation container.
- 5.2.1.3. Dosimeter placement in irradiation container.
- 5.2.1.4. Sterilization lot number.
- 5.2.1.5. Specified minimum and maximum dose radiation.
- 5.2.1.6. Sterilization date.
- 5.2.1.7. Dosimetric readings.

Specification	Revision	Issue Date	Originator:Manufacturing
S-024	00	6/27/01	George Makris

ENDOTEC, INC.

20 Valley Street, South Orange, New Jersey 07079

SPECIFICATION # S-024

Specification Title: **General Process and Quality Control Requirements and Inspection Criteria For The Cleaning Of Orthopedic Implants.**

1. SCOPE

1.1. This specification applies to the general process and quality control requirements and inspection criteria for the cleaning of orthopedic implants.

2. PURPOSE

2.1. This specification specifies general and minimum requirements for surface cleaning, method of surface cleaning and inspection criteria for orthopedic implants so as to remove environmental, handling and manufacturing process related contaminants. This shall apply when referenced on engineering drawings, process routers, Engineering specifications and or purchase orders. In process cleaning shall apply subsequent to all finishing operations where surface condition and cleanliness is necessary for the adequate inspection of the components. Final cleaning shall apply to all implants prior to final packaging.

3. 3.0 APPLICABLE DOCUMENTS

3.1. ASQC-C1 Specification of General Requirements for a Quality Control Program.

3.2. ASTM-F565 Practice for the Care and Handling of Orthopedic Implants and Instruments.

3.3. ASTM-F136 Specification for Titanium 6Al-4V ELI Alloy for Surgical Implant Applications.

3.4. ASTM-F67 Specification for Unalloyed Titanium for Surgical Implants.

3.5. Federal Standard 209 "Airborne Particulate Cleanliness Classes in Clean Room and Clean Zones".

3.6. ASNT TC-1A Supplement D Recommended Practice, Personnel Certification and Certification in Non-Destructive Testing.

4. DEFINITIONS

4.1 Orthopedic Implant is defined by F565 as a device introduced by surgically penetrating the skin or mucosa of the body with the intention that it remains within the body following surgery.

4.2 In-Process Cleaning is defined as cleaning necessary to remove process related contaminants that interfere with the implant's inspection, subsequent processing operations, or final performance. .

4.3 Final Cleaning is defined as, cleaning necessary to remove process, handling and environmental contaminants that may interfere with the implant's condition and performance standards during its use, prior to final packaging and sterilization of such implants.

Specification	Revision	Issue Date	Originator:Manufacturing
S-024	00	6/27/01	George Makris

5. QUALIFICATIONS OF INSPECTION PERSONNEL

5.1. All inspectors shall have a minimum vision rating in one eye as follows:

5.2. Near vision: Titmus Vision Tester 20/25 or better

5.3. Near vision acuity: Jaeger Type 2 at 14 inches or better

5.4. Color vision: Average (4 of 6 responses on Titmus test)

6. PROCESS / PROCEDURE DEFINITION

6.1. IN PROCESS PLASTICS:

6.1.1. The cleaning of plastic components is intended to remove all surface contaminants resulting from the manufacturing and handling of the components. All components shall be visually inspected for any defects such as surface damage or poor surface condition.

6.1.2. Implants in an unacceptable condition shall be segregated and the quality assurance manager shall be contacted for instructions as to their disposition.

6.1.3. Cleaning and drying of components shall be performed at temperatures compatible to the component's material so as not to compromise the mechanical or dimensional characteristics of the components.

6.1.4. Components shall be soaked in a detergent solution able to dissolve contaminants traceable to the method of manufacture.

6.1.5. Mechanical means compatible with the components material shall be employed to remove loose and lightly imbedded solid contaminants without further contaminating or altering the components surface.

6.1.6. Ultrasonically agitated detergent cleaning shall be employed for removing loose contaminants resulting from the manufacture and handling of the components.

6.1.7. Ultrasonically agitated rinsing shall be employed for removing detergent used in cleaning.

6.1.8. Final rinsing with commercially available distilled water shall be employed.

6.1.9. Air-drying at room temperature shall be employed as a final step.

6.2. IN PROCESS METALS:

6.2.1. All porous coated implants shall be protected from all solid particulate contaminants such as machining media, abrasives and dust by the use of water-soluble high purity gelatin. Temperature and solubility characteristics of masking media are to be considered so as not to compromise the in process performance and the later integral removal from implants. The protective media and other contaminants removal shall combine various methods that assure implant material integrity. It is recommended that a single step processes be avoided unless reliable controls exist.

6.2.2. It is recommended that the water-soluble high purity gelatin used is laced with dye penetrant such that its adequate removal is monitored by visual inspection.

6.2.3. The cleaning of metal components is intended to remove all surface contaminants resulting from the manufacturing and handling of the components. All components shall be visually inspected for any defects such as surface damage or poor surface condition.

6.2.4. Implants in an unacceptable condition shall be segregated and the quality assurance manager shall be contacted for instructions as to their disposition.

6.2.5. Cleaning and drying of components shall be performed at temperatures not exceeding 300 F.

6.2.6. Components shall be soaked in a detergent solution able to dissolve contaminants traceable to the method of manufacture.

6.2.7. Mechanical means compatible with the components material and surface finish shall be employed to remove loose and lightly imbedded solid contaminants without further contaminating or altering the components surface. These may include the use of soft brushes and high-pressure water jet.

6.2.8. Ultrasonically agitated detergent cleaning shall be employed for removing loose contaminants resulting from the manufacture and handling of the components.

6.2.9. Components shall be soaked in an alkaline detergent solution able to dissolve protein and cellulose based materials. This step shall be employed after standard detergent and mechanical means of cleaning, to assist in assuring no gelatin or polishing media remain entrapped in not readily visible surfaces of the components.

6.2.10. Ultrasonically agitated rinsing shall be employed for removing detergent used in cleaning.

6.2.11. Final rinsing with commercially available distilled water shall be employed.

6.2.12. Air-drying at temperatures not exceeding 300 F shall be employed as a final step. Other means such as forced air and water-absorbing paper may be used to remove excess water from porous coated and polished surfaces to accelerate the drying process and reduce environmental recontamination of the cleaned surfaces.

6.2.13. It is recommended that, to the extent practical, cleaning and rinsing fluid temperatures be elevated to a maximum of 140 F to improve efficiency of the cleaning process.

6.2.14. No component should be allowed to dry prior to the final distilled water rinse, to minimize staining or surface etching from solution chemicals due to evaporation.

6.3. FINAL CLEANING Prior to Packaging:

6.3.1. All implants shall be protected from all solid particulate and other environmental contaminants by the use of appropriate environmental controls that meet or exceed clean room 10,000 standards.

6.3.2. All components shall be visually inspected for any defects such as surface damage or poor surface condition prior to the final cleaning operation.

6.3.3. Implants in an unacceptable condition shall be segregated and the quality assurance manager shall be contacted for instructions as to their disposition.

6.3.4. Components shall be soaked in an Isopropyl alcohol bath to dissolve any contaminants common to normal handling and transit packaging of materials.

6.3.5. All implants shall be protected from subsequent recontamination by the use of lint and dust free gloves and the use of appropriate environmental controls that meet or exceed clean room 10,000 standards.

6.3.6. Air-drying at temperatures not exceeding 120 F shall be employed as a final step. Other means such as forced air and water-absorbing paper may be used to remove excess moisture from porous coated and polished surfaces to accelerate the drying process and reduce environmental recontamination of the cleaned surfaces and to minimize staining.

7. INSPECTION REQUIREMENTS

7.1. Receiving:

7.1.1. All implants shall be inspected by the cleaning facility for any readily visible surface defects or poor surface condition prior to cleaning.

7.2. Final Inspection:

Specification	Revision	Issue Date	Originator:Manufacturing
S-024	00	6/27/01	George Makris

7.2.1. All implants shall be visually inspected to verify the absence of all surface contamination such as staining, residues, embeds, fibers, etc, visible to the unaided eye as well as other damage resulting from handling during cleaning.

8. REPORTING AND DOCUMENTATION

8.1. All Implants shall be processed according to S016.

8.2. At the time of shipment the facility performing such cleaning operations shall provide a certificate of conformance to this specification, or adherence to other process requirements referencing this procedure. Such certificate shall contain, but not be limited to:
(1) Implant Lot Number quantities and date.

9. REJECTION & REWORK

9.1. All Implants, unless otherwise specified by the purchasing documentation or engineering specification, may be re-cleaned. Any cleaning stage may be repeated as necessary, on condition that all subsequent stages are also repeated to assure completeness of the cleaning process. Such activity does not require prior authorization by QA manager.

9.2. On determination that re-cleaning will not eliminate contaminants from the components they shall be rejected and Quality control shall be notified for final disposition.

ENDOTEC	Specification	Revision	Issue Date	Originator Quality Assurance
	S-021	B	11/11/99	

6.4.1.2. Quantitative or qualitative and/or statistically significant results:

6.4.1.3. References of the of background technical data:

6.4.1.4. Discussion of major problems and corrective action taken to solve them.

6.4.2. Processes shall be revalidated if changes are made to the equipment, product, packaging materials, or packaging process of the original validation.

7. FINAL PACKAGE TEST AND INSPECTION

7.1. The contract packager shall test for package and seal integrity per documented procedure for every run. The sampling plan shall be based upon AQL chosen for the run.

7.2. The external surface of the final outer pouch shall be inspected visually for defects such as:

7.2.1. Irregularities in or on the sterile barrier materials such as tears, cracks, holes, or fractures;

7.2.2. Presence of foreign materials;

7.2.3. Seal integrity (open or incomplete seals);

7.2.4. Presence of moisture or staining.

7.3. The final package shall be inspected for outer box label, package integrity and tamper evident seal.

7.4. The packager shall perform the final inspection per SLP0009.

7.5. Returned product that have tamper evident labels broken shall be inspected by QA for packaging integrity.

7.5.1. If determined that the inside and or outside pouches have not been opened, the product is not damaged or contaminated. QA shall put on new tamper evident labels, and release the newly sealed product back to Sales. This shall be documented and referenced in the Device History File. Tamper evident labels shall be controlled by QA; they shall be applied only by QA and those authorized by QA.

8. PACKAGE CERTIFICATION

8.1. All production runs shall be accompanied by certification of packaging, that includes purchase order number, packaging lot number and sample of the labels used for that run.

Procedure	Revision	Issue Date	Originator : Engineering
S-022	B	8/5/99	Mir Taher

ENDOTEC, INC.

20 Valley Street, South Orange , New Jersey 07079

SPECIFICATION # S-022

Specification Title: **Requirements for The Validation and Routine Monitoring of Sterilization by Gaseous Ethylene Oxide.**

1. SCOPE

1.1. This specification describes the requirement for the development, validation, process control, and monitoring of the sterilization of medical devices using ethylene oxide.

2. PURPOSE

2.1. This specification shall provide the specification and quality requirements for the validation and routine sterilization of medical devices using ethylene oxide, and shall conform to ISO 11135, and Health Care Industry standards. This specification shall be used and referenced on all purchase orders, travelers, etc..

3. APPLICABLE DOCUMENTS

3.1. ISO 9001 Quality Systems. Model for Quality Assurance in Design, Development, Production, installation, and Servicing.

3.2. ISO 11135 Validation and Routine Control of Ethylene Oxide Sterilization.

3.3. EN46001 Quality System Requirements for Medical Devices.

3.4. Vol. I AAMI Standards and Recommended Practices.

3.5. AAMI TIR On Process Validation for EtO Sterilization Microbiological Aspects.

3.6. ISO/TC194/DIS1C993-7.2 EtO Sterilization Residuals.

4. DEFINITIONS

4.1. **Aeration.** Part of the sterilization process during which ethylene oxide is desorb from the medical device until predetermined levels are reached.

4.2. **Bioburden.** The total number of viable microbes on a packaged item or medical device prior to the sterilization processing.

4.3. **Commissioning.** Obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications and that it functions within predetermined limits when operated in accordance with operational instructions.

4.4. **Conditioning.** Treatment of product within the sterilization cycle, but prior to sterilant admission, to attain a predetermined temperature and relative humidity throughout the sterilization load.

4.5. D- Value: **decimal reduction value.** Time (expressed in miniciles) required to secure inactivation of [illegible] the test organisms under stated exposure conditions.

Procedure	Revision	Issue Date	Originator : Engineering
S-022	B	8/5/99	*Mir Taher*

4.6. **Exposure Time.** Time for which the sterilizing chamber is maintained at the specified temperature, sterilant concentration, pressure, and humidity.

4.7. **Inoculated carrier.** Piece of supporting material on which a defined number of specified microorganisms has been deposited.

4.8. **Performance Qualification,** Obtaining and documenting evidence that the equipment as commissioned will produce acceptable product when operated in accordance with the process specification.

4.9. **Preconditioning,** (See **Conditioning**)

4.10. **Process Challenge Device,** Object that simulates the worst case of conditions, as they are given by the sterilizing agent, in the items of the goods to be sterilized.

4.11. **Process Development,** Documented program of studies that is performed to define the sterilization process based upon the product/packaging loading pattern and/or equipment limitations.

4.12. **Process Qualification,** Obtaining and documenting evidence that the sterilization process will produce acceptable health care products.

4.13. **Product Compatability,** Ability of the sterilization cycle to achieve the intended results without a detrimental effect on the product.

4.14. **Product Qualification.** Obtaining and documenting evidence health care product will be acceptable for its intended use after exposure to EtO.

4.15. **Sample.** The experimental unit that is either the whole medical device or unit, or a portion thereof, determined by weight, volume, or surface area, chosen to represent the bioburden validity.

4.16. **Sterile.** Condition of a medical device that is free from viable microorganisms.

4.17. **Sterility Assurance Level.** The expected probability of an item or unit being nonsterile after exposure to a valid sterilization process. SAL's range from 10^{-3} to 10^{-6} depending on product use.

4.18. **Sterility Assurance Level dose.** the dose in KGy required to achieve the desired SAL.

4.19. **Sterilizing Facility.** the place where sterilization and sterilization validation is performed, either in-house or at contract sterilizer.

4.20. **Validation.** Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality characteristics.

5. PROCEDURE VALIDATION

5.1. Validation shall be performed using method C, the Half cycle method of **AAMI/ANSI/ISO 11135** guidelines. The validation shall include:

5.1.1. **Commissioning;**
5.1.2. **Performance Qualification,** Physical;
5.1.3. **Performance Qualification,** Microbiological;
5.1.4. **Certification of Validation;**
5.1.5. **Process Control and Monitoring;**
5.1.6. **Product Release from Sterilization.**

5.2. **Commissioning,** it shall be associated with demonstrating that the equipment conforms to specification before performance qualification, and demonstrating that acceptable product will be produced when the commissioned equipment is used in accordance with documented procedures. The Sterilizing Facility is

Procedure	Revision	Issue Date	Originator : Engineering
S-022	B	8/5/99	Mir Taher

5.5. **Certification of Validation** The validation report should include the following:

5.5.1. Details of product sterilized:

5.5.2. The specification of the Sterilizer:

5.5.3. The Commissioning data:

5.5.4. Records of performance qualification, physical and micrbiological.

5.5.5. The validation protocol;

5.5.6. The documented procedures used:

5.5.7. Documented operating procedures including process control limits.

5.6. **Maintenance of Calibration Procedures**

5.6.1. **Revalidation,** Revalidation shall be performed to confirm that inadvertent process changes have not been made, and to demonstrate that the original validation report remains valid. Revalidation will include elements of recommissioning and requalifications. If recommissioning or requalification detects a process change, the commissioning and performance qualification may need to be done again. Previous validation and revalidation results should be considered in establishing the revalidation protocol. Data from the revalidation should be compared with records of the original validation to confirm that the original performance has been retained. The Sterilizing Facility is responsible for developing the protocol and performing the revalidation per ISO 11135 guidelines.

5.7. **Routine Sterilization, Control and Release**

5.7.1. The routine EtO sterilization of a medical device is critical to ensure device sterility, safety, and effectiveness. Consistant operating conditions should be maintained and monitored, and control of the EtO sterilization process should be designated.

5.7.2. Data shall be recorded and retained for each sterilization cycle to demonstrate that the sterilization process specification has been met. The data should include the following:

5.7.2.1. Temperature within the sterilization load during preconditioning.

5.7.2.2. Time of commencement and removal of the sterilization load from preconditioning for each sterilization load.

5.7.2.3. Time of commencement of the sterilization cycle of each sterilization load.

5.7.2.4. Temperature within the sterilization load during the sterilization cycle.

5.7.2.5. Humidity during conditioning as determined by direct measurement.

5.7.2.6. Pressure in the chamber during the sterilization cycle.

5.7.2.7. Evidence that EtO has been admitted to the sterilization chamber.

5.7.2.8. Concentration of EtO in the chamber determined by analysis.

5.7.2.9. Exposure time.

5.7.2.10. Aeration time.

5.7.3. Besides these parameters, Biological Indicators (BI's) shall be used in glassine (placed with the samples) and placed in an area that is the most difficult to sterilize. When the sterilization cycle is complete, the BI's shall be removed from the glassine and sent for testing. Based on the BI's results, the lot shall be released. There shall not be any positives in the BI's testing. The sterilizing Facility shall be responsible for proving the data as well as monitoring the sterilization process.

5.7.4. The other process parameters are by a sterilization and testing protocol developed by vendor and agreed upon by Endotec QA.

5.8. [illegible] Records

responsible for commissioning the equipment. They shall demonstrate that the equipment specifications for the preconditiong sterilization, and aeration equipment are met. The Contract Sterilizing Vendor shall also demonstrate documented evidence of calibration of all instrumentation for controlling the load condition, indicating, and recording the sterilization process. As part of preconditioning for temperature and humidity shall be monitored per ISO 11135 guidelines.

5.3. **Performance Qualification, Physical** Physical performance qualification shall be performed on the introduction of new product, significant changes to existing product in product design, packaging, sterilization load configuration or density, sterilization equipment, or process cycle. The effects of such changes on all stages of the sterilization including preconditioning and aeration should be determined. The Sterilizing Facility is responsible for performance qualification (physical) in accordance with ISO 11135 guidelines and shall furnish documentation as part of the validation revalidation reports. Performance qualification shall be performed in the chamber for both minimum and maximum load sizes during validation using the half cycle method. Temperature profiles of the sterilization load shall be determined for each loading pattern. The location of the probes throughout the sterilization load should be selected to determine the maximum temperature variation, and take into account hot or cold spots located during commissioning. Physical performance factors should be determined for the specified loading patterns in order to prepare the operating specification. These factors should include:

5.3.1. The depth and rate of attainment of vacuum;

5.3.2. The chamber leak rate (performed either under vacuum for sub-atmospheric cycles, or under vacuum and at pressure for super-atmospheric cycles.)

5.3.3. The pressure rise or injection of steam during the conditioning phase.

5.3.4. The pressure rise and rate of attainment on admission of EtO and correlation of factors with [illegible] is intended to monitor gas concentration.

5.3.5. The depth and rate of attainment of vacuum used to remove EtO.

5.3.6. The pressure rise and rate of attainment of pressure on admission of air.

5. **Performance Qualification, Microbiological** Microbiological performance qualification shall be performed on the introduction of new product, significant changes to existing product in product design, packaging, sterilization load configuration or density, sterilization equipment, or process cycle. The effects of such changes on all stages of the sterilization including preconditioning and aeration should be determined. The Sterilizing Facility is responsible for performance qualification (microbiological) in accordance with ISO 11135 guidelines and shall furnish documentation as part of their validation revalidation reports. Since the number and resistance of microorganisms on any particular item prior to sterilization is unknown, the efficiency of a sterilization cycle is demonstrated by conducting a study to determine the naturally occurring bioburden on the product prior to sterilization vs. known resistance (Biological Indicator) BI's. BI's shall be used with known microorganisms. The selection of the type of BI's to be used is the responsibility of the Sterilizing Facility and shall satisfy the requirements of ISO 11135 and AAMI TIR guidelines. The resistance of these microorganisms shall be used to establish the sterilization cycle specification. If the naturally occurring bioburden or CFU's are less than 1,000, BI's should be placed in the part of the product that is most difficult to sterilize. If the design of the product is such that a BI cannot be accommodated, the product shall be inoculated with the microorganism to provide a known number of viable spores. BI's shall be used and should be placed in such locations where sterilization conditions are the most difficult to achieve. Microbiological performance qualification shall be carried out using Method C, the Half cycle method of AAMI TIR 28/ISO **11135.** This method involves determination of the minimum time of exposure to EtO, with all other process parameters, except time remaining constant, at which there are no survivors. Two further experiments should be performed to confirm the minimum time. Both should show no growth from [illegible]. The specified exposure time should be at least double the minimum time.

Procedure	Revision	Issue Date	Originator : Engineering
S-023	C	7/14/04	*Mir Taher*

ENDOTEC, INC.

50 South Center Street, Orange, New Jersey 07050

SPECIFICATION # S-023

Specification Title: **Requirements for The Validation and Routine Monitoring of Sterilization by Gamma Radiation.**

1. SCOPE

1.1. This specification describes the requirement for the development, validation, process control, and monitoring of the sterilization of medical devices using gamma radiation.

2. PURPOSE

2.1. This specification shall provide the specification and quality requirements for the validation and routine sterilization of medical devices using gamma radiation, and shall conform to ISO and Health Care Industry standards. This specification shall be used and referenced on all purchase orders, travelers, etc..

3. APPLICABLE DOCUMENTS

3.1. ISO 9000A Quality Systems, Model for Quality Assurance in Design, Development, Production, Installation, and Servicing.

3.2. ANSI/AAMI/ISO **11137:1994/A1:2002** Requirements for Validation and Routine Control – Radiation sterilization.

3.3. ISO-13485 Quality System Requirements for Medical Devices.

3.4. Vol. 2 AAMI Standards and Recommended Practices.

3.5. AAMI TIR 27:**2001** Microbiological Methods for Gamma Irradiation Sterilization of Medical Devices.

3.6. ANSI/AAMI **ST32** Guideline for gamma radiation sterilization

4. DEFINITIONS

4.1. **Absorbed dose**, the quantity of radiation energy absorbed per unit of mass. This quantity is usually refered to simply as "dose".

4.2. **Dosimeter**, a device or system having a reproducible, measureable response to radiation, which may be used to measure the quantity of absorbed dose in a given material.

5. PROCEDURE

5.1. **Sterilization and packaging**

5.1.1. All devices covered by this specification shall be sterilized and packaged in accordance with ANSI/AAMI ISO/111137:1994/A1:2002 using a dose of 25kGy .

5.2. Dose [illegible] ESTABLISHMENT

5.2.1. The establishment for the dose of 25kGy shall be accomplished by the procedure of AAMI TIR27:2001

Procedure	Revision	Issue Date	Originator : Engineering
S-022	B	8/5/99	Mir Taher

5.8.1. EtO for sterilization of medical devices at acceptable residual levels prove no risk to the patient in normal product use, but any exposure of more them normal may cause or is known to exhibit a number of biological effects, and consideration should be given to EC (Ethylene Chlorohydrin) and EG (Ethylene Glycol) because of these potentially harmful effects.

5.8.2. The acceptable levels for Endotec devices shall be EtO 0.1mg/day ADD (averaged daily dose); EC 2mg/day ADD; and in ppm (parts per million) it is 100, 100, 1000 for EtO, EC and EG.

5.8.3. The method for determining EtO, EC, and EG residuals is the responsibility of the Sterilizing Facility and shall satisfy the requirement of ISO 10993.

5.8.4. For product lots processed 5 or less in a year, the release of product for Eto, EC, and EG residuals shall be performed for each individual lot, i.e. products without dissipation curve data.

5.8.5. For product lots processed 5 or more in a year, the release of product for Eto, EC, and EG residuals shall be performed per the procedure for product release using residual dissipation curves.

5.9. Reports

5.9.1. Validation Reports;

5.9.2. Revalidation Reports;

5.9.3. Routine Sterilization Reports.

Procedure	Revision	Issue Date	Originator : Engineering
S-023	C	7/14/04	Mir Taher

ENDOTEC, INC.

50 South Center Street, Orange, New Jersey 07050

SPECIFICATION # S-023

Specification Title: **Requirements for The Validation and Routine Monitoring of Sterilization by Gamma Radiation.**

1. SCOPE

1.1. This specification describes the requirement for the development, validation, process control, and monitoring of the sterilization of medical devices using gamma radiation.

2. PURPOSE

2.1. This specification shall provide the specification and quality requirements for the validation and routine sterilization of medical devices using gamma radiation, and shall conform to ISO and Health Care Industry standards. This specification shall be used and referenced on all purchase orders, travelers, etc..

3. APPLICABLE DOCUMENTS

3.1. ISO 90001 Quality Systems. Model for Quality Assurance in Design, Development, Production, Installation, and Servicing.

3.2. ANSI/AAMI/ISO 11137:1994/AI:2002 Requirements for Validation and Routine Control – Radiation Sterilization.

3.3. EN460001 Quality System Requirements for Medical Devices.

3.4. Vol. 1 AAMI Standards and Recommended Practices.

3.5. AAMI TIR 27:2001 Microbiological Methods for Gamma Irradiation Sterilization of Medical Devices.

3.6. ANSI/AAMI ST32 Guideline for gamma radiation sterilization

4. DEFINITIONS

4.1. **Absorbed dose**, the quantity of radiation energy absorbed per unit of mass. This quantity is usually refered to simply as 'dose'.

4.2. **Dosimeter**, a device or system having a reproducible, measureable response to radiation, which may be used to measure the quantity of absorbed dose in a given material.

5. PROCEDURE

5.1. **Sterilization and packaging**

5.1.1 All devices covered by this specification shall be sterilized and packaged in accordance with ANSI/AAMI/ISO/111137:1994/A1:2002 using a dose of 25kGy .

5.2. DOSE SUBSTANTIATION

5.2.1 The substantiation for the dose of 25kGy shall be accomplished by the procedure of AAMI TIR27:2001

Procedure	Revision	Issue Date	Originator : Engineering
S-023	C	7/14/04	*Mir Taher*

5.2.2 **Processing Records,** The process specification should require the following information be recorded and reviewed by authorized individuals and maintained in the process documentation.

- 5.2.1.1. Incoming product count (number of boxes).
- 5.2.1.2. Product loading pattern in irradiation container.
- 5.2.1.3. Dosimeter placement in irradiation container.
- 5.2.1.4. Sterilization lot number.
- 5.2.1.5. Specified minimum and maximum dose radiation.
- 5.2.1.6. Sterilization date.
- 5.2.1.7. Dosimetric readings.

Procedure	Revision	Issue Date	Originator : Engineering
S-023	C	7/14/04	*Mir Taher*

5.2.2 **Processing Records,** The process specification should require the following information be recorded and reviewed by authorized individuals and maintained in the process documentation.

- 5.2.1.1. Incoming product count (number of boxes).
- 5.2.1.2. Product loading pattern in irradiation container.
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- 5.2.1.7. Dosimetric readings.

Specification	Revision	Issue Date	Originator:Manufacturing
S-024	00	6/27/01	George Makris

ENDOTEC, INC.

20 Valley Street, South Orange, New Jersey 07079

SPECIFICATION # S-024

Specification Title: **General Process and Quality Control Requirements and Inspection Criteria For The Cleaning Of Orthopedic Implants.**

1. SCOPE

1.1. This specification applies to the general process and quality control requirements and inspection criteria for the cleaning of orthopedic implants.

2. PURPOSE

2.1. This specification specifies general and minimum requirements for surface cleaning, method of surface cleaning and inspection criteria for orthopedic implants so as to remove environmental, handling and manufacturing process related contaminants. This shall apply when referenced on engineering drawings, process routers, Engineering specifications and or purchase orders. In process cleaning shall apply subsequent to all finishing operations where surface condition and cleanliness is necessary for the adequate inspection of the components. Final cleaning shall apply to all implants prior to final packaging.

3. 3.0 APPLICABLE DOCUMENTS

3.1. ASQC-C1 Specification of General Requirements for a Quality Control Program.

3.2. ASTM-F565 Practice for the Care and Handling of Orthopedic Implants and Instruments.

3.3. ASTM-F136 Specification for Titanium 6Al-4V ELI Alloy for Surgical Implant Applications.

3.4. ASTM-F67 Specification for Unalloyed Titanium for Surgical Implants.

3.5. Federal Standard 209 "Airborne Particulate Cleanliness Classes in Clean Room and Clean Zones".

3.6. ASNT TC-1A Supplement D Recommended Practice, Personnel Certification and Certification in Non-Destructive Testing.

4. DEFINITIONS

4.1. Orthopedic Implant is defined by F565 as a device introduced by surgically penetrating the skin or mucosa of the body with the intention that it remains within the body following surgery.

4.2. In-Process Cleaning is defined as cleaning necessary to remove process related contaminants that interfere with the implant's inspection, subsequent processing operations, or final performance. .

4.3. Final Cleaning is defined as, cleaning necessary to remove process, handling and environmental contaminants that may interfere with the implant's condition and performance standards during its use, prior to final packaging and sterilization of such implants.

6.2.7. Mechanical means compatible with the components material and surface finish shall be employed to remove loose and lightly imbedded solid contaminants without further contaminating or altering the components surface. These may include the use of soft brushes and high-pressure water jet.

6.2.8. Ultrasonically agitated detergent cleaning shall be employed for removing loose contaminants resulting from the manufacture and handling of the components.

6.2.9. Components shall be soaked in an alkaline detergent solution able to dissolve protein and cellulose based materials. This step shall be employed after standard detergent and mechanical means of cleaning, to assist in assuring no gelatin or polishing media remain entrapped in not readily visible surfaces of the components.

6.2.10. Ultrasonically agitated rinsing shall be employed for removing detergent used in cleaning.

6.2.11. Final rinsing with commercially available distilled water shall be employed.

6.2.12. Air-drying at temperatures not exceeding 300 F shall be employed as a final step. Other means such as forced air and water-absorbing paper may be used to remove excess water from porous coated and polished surfaces to accelerate the drying process and reduce environmental recontamination of the cleaned surfaces.

6.2.13. It is recommended that, to the extent practical, cleaning and rinsing fluid temperatures be elevated to a maximum of 140 F to improve efficiency of the cleaning process.

6.2.14. No component should be allowed to dry prior to the final distilled water rinse, to minimize staining or surface etching from solution chemicals due to evaporation.

6.3. **FINAL CLEANING Prior to Packaging:**

6.3.1. All implants shall be protected from all solid particulate and other environmental contaminants by the use of appropriate environmental controls that meet or exceed clean room 10,000 standards.

6.3.2. All components shall be visually inspected for any defects such as surface damage or poor surface condition prior to the final cleaning operation.

6.3.3. Implants in an unacceptable condition shall be segregated and the quality assurance manager shall be contacted for instructions as to their disposition.

6.3.4. Components shall be soaked in an Isopropyl alcohol bath to dissolve any contaminants common to normal handling and transit packaging of materials.

6.3.5. All implants shall be protected from subsequent recontamination by the use of lint and dust free gloves and the use of appropriate environmental controls that meet or exceed clean room 10,000 standards.

6.3.6. Air-drying at temperatures not exceeding 120 F shall be employed as a final step. Other means such as forced air and water-absorbing paper may be used to remove excess moisture from porous coated and polished surfaces to accelerate the drying process and reduce environmental recontamination of the cleaned surfaces and to minimize staining.

7. INSPECTION REQUIREMENTS

7.1. **Receiving:**

7.1.1. All implants shall be inspected by the cleaning facility for any readily visible surface defects or poor surface condition prior to cleaning.

7.2. **Final Inspection:**

ENDOTEC

Specification	Revision	Issue Date	Originator:Manufacturing
S-024	00	6/27/01	George Makris

5. QUALIFICATIONS OF INSPECTION PERSONNEL

5.1. All inspectors shall have a minimum vision rating in one eye as follows:

5.2. Near vision: Titmus Vision Tester 20/25 or better

5.3. Near vision acuity: Jaeger Type 2 at 14 inches or better

5.4. Color vision: Average (4 of 6 responses on Titmus test)

6. PROCESS / PROCEDURE DEFINITION

6.1. IN PROCESS PLASTICS:

6.1.1. The cleaning of plastic components is intended to remove all surface contaminants resulting from the manufacturing and handling of the components. All components shall be visually inspected for any defects such as surface damage or poor surface condition.

6.1.2. Implants in an unacceptable condition shall be segregated and the quality assurance manager shall be contacted for instructions as to their disposition.

6.1.3. Cleaning and drying of components shall be performed at temperatures compatible to the component's material so as not to compromise the mechanical or dimensional characteristics of the components.

6.1.4. Components shall be soaked in a detergent solution able to dissolve contaminants traceable to the method of manufacture.

6.1.5. Mechanical means compatible with the components material shall be employed to remove loose and lightly imbedded solid contaminants without further contaminating or altering the components surface.

6.1.6. Ultrasonically agitated detergent cleaning shall be employed for removing loose contaminants resulting from the manufacture and handling of the components.

6.1.7. Ultrasonically agitated rinsing shall be employed for removing detergent used in cleaning.

6.1.8. Final rinsing with commercially available distilled water shall be employed.

6.1.9. Air-drying at room temperature shall be employed as a final step.

6.2. IN PROCESS METALS:

6.2.1. All porous coated implants shall be protected from all solid particulate contaminants such as machining media, abrasives and dust by the use of water-soluble high purity gelatin. Temperature and solubility characteristics of masking media are to be considered so as not to compromise the in process performance and the later integral removal from implants. The protective media and other contaminants removal shall combine various methods that assure implant material integrity. It is recommended that a single step processes be avoided unless reliable controls exist.

6.2.2. It is recommended that the water-soluble high purity gelatin used is laced with dye penetrant such that its adequate removal is monitored by visual inspection.

6.2.3. The cleaning of metal components is intended to remove all surface contaminants resulting from the manufacturing and handling of the components. All components shall be visually inspected for any defects such as surface damage or poor surface condition.

6.2.4. Implants in an unacceptable condition shall be segregated and the quality assurance manager shall be contacted for instructions as to their disposition.

6.2.5. Cleaning and drying of components shall be performed at temperatures not exceeding 300 F.

6.2.6. Components shall be soaked in a detergent solution able to dissolve contaminants traceable to the method of manufacture.

ENDOTEC

Specification	Revision	Issue Date	Originator:Manufacturing
S-024	00	6/27/01	George Makris

7.2.1. All implants shall be visually inspected to verify the absence of all surface contamination such as staining, residues, embeds, fibers, etc, visible to the unaided eye as well as other damage resulting from handling during cleaning.

8. REPORTING AND DOCUMENTATION

8.1. All Implants shall be processed according to S016.

8.2. At the time of shipment the facility performing such cleaning operations shall provide a certificate of conformance to this specification, or adherence to other process requirements referencing this procedure. Such certificate shall contain, but not be limited to:
(1) Implant Lot Number quantities and date.

9. REJECTION & REWORK

9.1. All Implants, unless otherwise specified by the purchasing documentation or engineering specification, may be re-cleaned. Any cleaning stage may be repeated as necessary, on condition that all subsequent stages are also repeated to assure completeness of the cleaning process. Such activity does not require prior authorization by QA manager.

9.2. On determination that re-cleaning will not eliminate contaminants from the components they shall be rejected and Quality control shall be notified for final disposition.